RECORD AND BRIEFS

15-1039 No.

FEB 16 2016

In The

Supreme Court of the United States

SANDOZ INC., PETITIONER,

v.

AMGEN INC. AND AMGEN MANUFACTURING LIMITED.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

In the Biologics Price Competition and Innovation Act of 2009 ("BPCIA"), Congress created an abbreviated regulatory pathway for the Food and Drug Administration ("FDA") to license "biosimilar" products—i.e., products that are "highly similar" to approved biological products. 42 U.S.C. § 262(i)(2). The BPCIA's "Notice of commercial marketing" provision states that a biosimilar applicant shall provide notice to the incumbent seller of the biological product "not later than 180 days *before the date of the first commercial marketing* of the biological product licensed under" this abbreviated pathway. *Id.* § 262(*l*)(8)(A) (emphasis added).

The Federal Circuit concluded that a biosimilar applicant "may only give effective notice of commercial marketing *after* the FDA has licensed its product." App., *infra*, 20a (emphasis added). As the dissenting judge recognized, the Federal Circuit turned this mere notice provision into a grant of 180 days of additional exclusivity for all biological products beyond the exclusivity period Congress expressly provided—delaying the launch of all future biosimilars by six months. The Federal Circuit transformed the notice provision into a stand-alone requirement unconnected to the patent resolution provisions of the BPCIA. It also disregarded the only remedy provided by Congress—the right to initiate

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patent litigation—and instead created its own extra-statutory injunctive remedy to bar the launch of FDA-approved biosimilars.

The questions presented are:

Whether notice of commercial marketing given before FDA approval can be effective and whether, in any event, treating Section 262(*l*)(8)(A) as a stand-alone requirement and creating an injunctive remedy that delays all biosimilars by 180 days after approval is improper.

PARTIES TO THE PROCEEDING AND RULE 29.6 CORPORATE DISCLOSURE STATEMENT

The parties to the proceeding are listed in the caption.[1]

Pursuant to Rule 29.6, petitioner Sandoz Inc. states the following:

Sandoz Inc. is an indirect, wholly owned subsidiary of Novartis AG, which trades on the SIX Swiss Exchange under the ticker symbol NOVN and whose American Depository Shares are publicly traded on the New York Stock Exchange under the ticker symbol NVS.

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[1] Amgen Inc. and Amgen Manufacturing Limited are both respondents in this Court. This petition refers to those entities collectively as "Amgen."

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PETITION FOR A WRIT OF CERTIORARI

Petitioner Sandoz Inc. respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit.

OPINIONS BELOW

The opinion of the court of appeals (App., *infra*, 1a-55a) is reported at 794 F.3d 1347. The opinion of the district court (App., *infra*, 56a-84a) is unreported but is available at 2015 WL 1264756.

JURISDICTION

The court of appeals entered judgment on July 21, 2015. Timely rehearing petitions were denied on October 16, 2015. App., *infra*, 85a-86a. On December 29, 2015, the Chief Justice extended the time for Sandoz to petition for a writ of certiorari to and including February 16, 2016. This Court's jurisdiction is invoked under 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

The BPCIA, Pub. L. No. 111-148, §§ 7001-7003, 124 Stat. 119, 804-21 (2010), and the relevant provisions of Titles 28, 35, and 42 of the United States Code amended by the BPCIA are reprinted in the appendix. App., *infra*, 87a-163a. Section 262(*l*)(8)(A) of Title 42 provides:

> **(A) Notice of commercial marketing**
>
> The subsection (k) applicant shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k).

INTRODUCTION

Congress enacted the BPCIA as part of the Patient Protection and Affordable Care Act to create competition in the biologic pharmaceuticals market and to reduce prices. Biologics are used to treat numerous medical conditions. *See* 42 U.S.C. § 262(i)(1). In contrast to chemically synthesized drugs, biologics "are isolated from a variety of natural sources—human, animal, or microorganism." FDA, *What are "Biologics" Questions and Answers*.[1] Biologics "often represent the cutting-edge of biomedical research and, in time, may offer the most effective means to treat a variety of medical illnesses and conditions that presently have no other treatments available." *Ibid.*

Biosimilars are "highly similar" to approved biological products, which the BPCIA refers to as "reference product[s]." 42 U.S.C. § 262(i)(2). The development of a biosimilar version of a biologic is generally much more expensive and time-consuming than the development of a generic version of a chemically synthesized drug. A Federal Trade Commission ("FTC") report estimates that biosimilars are "likely to take eight to ten years to develop, and their development will likely cost between $100 and $200 million"—in contrast to the three to five years and $1 to $5 million it typically costs to develop a generic

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[1] http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CBER/ucm133077.htm (last visited Feb. 12, 2016).

version of a chemically synthesized drug. FTC, *Emerging Health Care Issues: Follow-on Biologic Drug Competition* iii (June 2009) ("FTC Report").[2]

When Congress passed the BPCIA, purchases of biologics represented 21% of the $307 billion spent annually on medicines, and spending on biologics was increasing materially. CA JA A389-A391. The record before Congress showed that more competition in the biologics market could save government and private payors tens of billions of dollars. *E.g.*, Judith A. Johnson, Cong. Research Serv., RL34045, *FDA Regulation of Follow-On Biologics* 4 (2010).[3] Before the BPCIA's enactment, the FTC predicted that biosimilars would enter the market "at price discounts between 10 and 30 percent" off the reference product's price, and that the incumbent seller of the biological product—called the "reference product sponsor" in the BPCIA—would "respond aggressively and offer competitive discounts." FTC Report, *supra*, at 23. The Congressional Budget Office ("CBO") estimated that the introduction of biosimilars "would reduce total expenditures on biologics in the United States * * * by about $25 billion over the 2009-2018 period."

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[2] https://www.ftc.gov/sites/default/files/documents/reports/emerging-health-care-issues-follow-biologic-drug-competition-federal-trade-commission-report/p083901biologicsreport.pdf.

[3] https://primaryimmune.org/advocacy_center/pdfs/health_care_reform/Biosimilars_Congressional_Research_Service_Report.pdf.

CBO Cost Estimate, *S. 1695: Biologics Price Competition and Innovation Act of 2007* 1 (June 25, 2008).[4] The CBO projected that savings for the federal government alone would be $7 billion from 2010 to 2019. Letter from CBO Dir. Douglas W. Elmendorf to Hon. Nancy Pelosi, Speaker U.S. House of Rep., Table 5 at 10 (Mar. 20, 2010).[5]

To provide more direct competition, the BPCIA created an abbreviated regulatory pathway for FDA approval of biosimilars, allowing a biosimilar applicant to rely in part on the previous approval of the sponsor's reference product. App., *infra*, 4a-5a; 42 U.S.C. § 262(i)(2), (k). At the same time and in order "[t]o balance innovation and price competition," Congress provided sponsors up to twelve years of market exclusivity against follow-on biosimilar products—regardless of whether the sponsor has any valid patent claims covering the biosimilar. App., *infra*, 5a-6a; *see* 42 U.S.C. § 262(k)(7)(A).

Congress also provided for early resolution of patent disputes, by creating new artificial infringement actions that can be brought before FDA approval of a biosimilar and before any actual infringement occurs. Congress did not, however, link FDA approval of biosimilars to the pendency or outcome of any

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[4] https://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/94xx/doc9496/s1695.pdf.

[5] https://www.cbo.gov/sites/default/files/111th-congress-2009-2010/costestimate/amendreconprop.pdf.

patent suit. Rather, the FDA can license a biosimilar immediately upon expiration of the statutorily determined exclusivity period for the reference product. For a product sponsor to enjoin the marketing of a competing biosimilar, it must bring a patent infringement suit and make the requisite showing for a patent-based injunction.

In a fragmented decision, the Federal Circuit has disrupted the careful balance struck by Congress between competition and innovation. If not reversed, the Federal Circuit's ruling will delay access by patients to all biosimilars for six months longer than Congress intended. The Federal Circuit reached that result by adding an extra-textual limitation to the BPCIA's "Notice of commercial marketing" provision. That provision calls for "notice to the reference product sponsor not later than 180 days *before the date of the first commercial marketing* of the biological product licensed under subsection (k)," i.e., the abbreviated biosimilar pathway. 42 U.S.C. § 262(*l*)(8)(A) (emphasis added). The Federal Circuit held that an applicant "may only give effective notice of commercial marketing *after* the FDA has licensed its product." App., *infra*, 20a (emphasis added).

A majority of the Federal Circuit panel then enforced that erroneous reading by divorcing that provision from the BPCIA's patent resolution regime and replacing the remedies expressly provided in the BPCIA with a new remedy: "a 180-day injunction beyond the express twelve-year statutory exclusivity period." App., *infra*, 43a-44a (Chen, J., dissenting).

As Judge Chen recognized in dissent, the majority effectively awarded sponsors "an extra-statutory exclusivity windfall" of 180 days more than Congress expressly granted. App., *infra*, 44a (Chen, J., dissenting). The Federal Circuit's decision cannot be squared with the BPCIA's text and purpose, and it conflicts with this Court's precedents. As the district court observed, if Congress had wanted to add six months to the statutory exclusivity period, "it could not have chosen a more convoluted method of doing so." App., *infra*, 76a.

By its plain terms, the notice of commercial marketing provision simply calls for 180 days' notice *before* a biosimilar is marketed. Regardless of whether notice is given before or after FDA approval of the biosimilar, the notice would serve the statute's purpose of giving the reference product sponsor at least 180 days to initiate suit. But special notice after FDA approval would be superfluous, as FDA licensure is a public act. The Federal Circuit reached its erroneous conclusion by reading too much into the word "licensed" in subsection (*l*)(8)(A). That adjective merely refers to the biosimilar product that will be marketed, which will be licensed by the time of marketing. Nothing in the text provides that an applicant must wait until the FDA publicly approves its biosimilar, then provide "notice" of its self-evident intent to market that approved biosimilar, and then wait six months more before marketing its product.

The Federal Circuit compounded this error by disconnecting Section 262(*l*)(8)(A) from the BPCIA's

patent resolution regime and by creating a new remedy nowhere provided by the BPCIA: an injunction against commercial marketing until 180 days after post-approval notice is given. If Congress had so intended, it knew how to stay FDA approval for 180 days; it also knew how to authorize injunctions to enforce the notice provision. It did neither. Instead, it provided sponsors with a powerful remedy: a patent suit for artificial infringement that could be brought even before FDA approval. 42 U.S.C. § 262(*l*)(9)(B), (C); 35 U.S.C. § 271(e)(2)(C). Although Amgen brought such a suit, it made no attempt (and still has not) to seek an injunction based on any alleged patent infringement by Sandoz.

Without any such patent showing by Amgen, the plain terms of the BPCIA authorized Sandoz to make its biosimilar filgrastim product Zarxio® immediately available to cancer patients upon FDA approval: (1) Sandoz already had provided Amgen more than 180 days' notice of its intent to market, giving Amgen time to bring suit (which it did) and seek a patent-based injunction (which it did not), and (2) any statutory exclusivity period had expired, as Amgen already had enjoyed 24 years of exclusivity. *See* App., *infra*, 8a-9a. Instead, due to the Federal Circuit's erroneous interpretation of the notice of commercial marketing provision, competition was excluded from the market well beyond the exclusivity period granted by Congress, and cancer patients had to wait many months *after* FDA approval of Sandoz's product for access to more affordable medicine.

This issue is critically important. As one of the several amici supporting Sandoz's en banc petition explained, "the provision at issue here is a key element of a key statute governing an industry at the vanguard of health care delivery in the 21st Century."[6] Absent intervention from this Court, the Federal Circuit's ruling in this case will apply nationwide to delay the availability of *every* FDA-approved biosimilar for six months longer than Congress intended. Given the importance of this issue to patients, payors (including the federal government), and pharmaceutical companies, that delay should not be allowed to persist without this Court's review.

STATEMENT

A. Statutory Background

Congress struck a careful balance in the BPCIA between facilitating prompt access to cost-saving biosimilars and promoting innovation in biological products. BPCIA § 7001(b), 124 Stat. at 804 (reproduced at App., *infra*, 87a-126a). The statute allows an applicant to rely in part on the sponsor's license for the approved reference product in order to speed biosimilar market entry. 42 U.S.C. § 262(k). In exchange, the BPCIA gives biologics sponsors a total of 12 years without biosimilar competition: the FDA cannot "ma[k]e effective" approval of a biosimilar "until the date that is 12 years after the date on

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[6] Hospira, Inc., et al. *Amici Curiae* Br., CAFC Dkt. No. 140, at 4.

which the reference product was first licensed" by the FDA. *Id.* § 262(k)(7)(A).

The BPCIA also facilitates early resolution of potential patent disputes in order to speed biologics to market. To this end, the BPCIA made interlocking amendments to Titles 28, 35, and 42 of the United States Code. Pub. L. No. 111-148, 124 Stat. 804 (codified at 28 U.S.C. § 2201(b); 35 U.S.C. § 271(e)(2)(C), (4)(D), (6); 42 U.S.C. § 262(k)-(m)) (reproduced at App., *infra*, 127a-163a). In particular, the BPCIA amended the Patent Act to make submission of a biosimilar application to the FDA an artificial act of infringement under certain circumstances. 35 U.S.C. § 271(e)(2)(C). That provision allows a declaratory judgment action on patent infringement and validity before any actual infringement is imminent. *Cf. Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990) (discussing Congress's creation of an "artificial act of infringement" in order to "enable the judicial adjudication" of patent claims). Who can bring such an action, when, and for what relief depends on the actions or inactions at each step of a multi-step information exchange process between the applicant and the sponsor regarding the sponsor's possible patent claims. 35 U.S.C. § 271(e)(2)(C), (4), (6); 28 U.S.C. § 2201(b); 42 U.S.C. § 262(*l*)(2)-(9).

Congress spelled out the actions the applicant or sponsor "shall" take to start and continue the process. Under the first step of the exchange process, the applicant provides a copy of its biosimilar application to the sponsor within 20 days after the FDA accepts

the application for review. 42 U.S.C. § 262(*l*)(2)(A). In later steps, the parties exchange lists of patents for which they believe a claim of patent infringement could reasonably be asserted; exchange their respective positions on infringement, validity, and enforceability; and negotiate regarding the patents for which an immediate infringement action may be brought. *Id.* § 262(*l*)(3)-(5).

Congress also spelled out exactly what happens if a party declines to follow a particular step in the information exchange process. For example, if the applicant does not take the first step (i.e., provide its biosimilar application to the sponsor within 20 days of its acceptance by the FDA), the BPCIA expressly lays out a separate path for resolving any patent disputes: patent infringement litigation, with the scope and timing at the sole discretion of the reference product sponsor. *Id.* § 262(*l*)(9)(C); 35 U.S.C. § 271(e)(2)(C)(ii). And even if the patent exchange process is initiated, and regardless of whether it is completed, the end result is that the reference product sponsor or the applicant can bring suit for patent infringement. The contours of that suit are determined by the actions that the parties did or did not take in the information exchange process. 35 U.S.C. § 271(e)(2)(C), (4), (6); 42 U.S.C. § 262(*l*)(6), (9)(A)-(B).

As particularly relevant to this petition, the BPCIA includes a provision entitled "Notice of commercial marketing." 42 U.S.C. § 262(*l*)(8)(A). That provision states:

> The subsection (k) applicant [i.e., the biosimilar applicant] shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k) [i.e., the biosimilar product].

Ibid. This provision provides notice to the sponsor that a biosimilar is at least six months from coming to market and allows the sponsor to seek a preliminary injunction to enforce any patent claims it has not yet been able to enforce in the exchange process. *Id.* § 262(*l*)(8)(A)-(B).

Critically, the BPCIA also expressly specifies a consequence for not providing the notice of commercial marketing. Where the applicant has initiated the patent exchange process and the sponsor has provided its initial list of possibly relevant patents to the applicant, the consequence of the applicant's not providing the notice is that "the reference product sponsor, but not the [biosimilar] applicant, may bring an action" for a declaration of infringement, validity, or enforceability of any patent on that list. *Id.* § 262(*l*)(9)(B). And where the applicant did not initiate the patent exchange process by providing its biosimilar application, that non-provision of the application already had triggered the sponsor's ability to bring an action for a declaration of infringement of any patent. *See* 35 U.S.C. § 271(e)(2)(C)(ii); 42 U.S.C. § 262(*l*)(9)(C).

B. Factual Background

1. Sandoz's biosimilar application

When Sandoz applied for FDA approval of its filgrastim biosimilar, Amgen already had marketed filgrastim under the brand name Neupogen® for 24 years—twice the 12-year period Congress deemed sufficient to encourage innovation in biologics. App., *infra*, 8a; 42 U.S.C. § 262(k)(7)(A).

On July 7, 2014, the FDA accepted for review Sandoz's application for biosimilar filgrastim. App., *infra*, 8a. The next day, Sandoz notified Amgen that Sandoz had filed the application and that Sandoz expected FDA approval in the first half of 2015. *Ibid.* Sandoz also provided notice that it intended to launch its biosimilar filgrastim product in the United States immediately upon FDA approval. *Ibid.* The FDA had publicly stated a goal of reviewing and acting on a majority of biosimilar applications within 10 months of receipt. *See* FDA, *Biosimilar Biological Product Authorization Performance Goals and Procedures Fiscal Years 2013 Through 2017* 3.[7]

In light of Amgen's public statements in filings with the Securities and Exchange Commission that it had no material, unexpired patents for filgrastim, Sandoz determined that subjecting itself to an immediate patent suit was the quickest path to resolution

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[7] http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/UCM281991.pdf.

of any patent claims. CA JA A915, A960, A1495-A1497. On July 25, 2014, Sandoz therefore informed Amgen that it had "opted not to provide Amgen with Sandoz's biosimilar application within 20 days of the FDA's notification of acceptance" and that the BPCIA thus entitled Amgen to bring a declaratory judgment action for patent infringement against Sandoz. App., *infra*, 8a; *see* 42 U.S.C. § 262(*l*)(9)(C).

2. Proceedings in district court

a. Several months later—in October 2014—Amgen sued Sandoz, asserting three claims. App., *infra*, 9a.

First, Amgen brought a claim under California's Unfair Competition Law ("UCL"), Cal. Bus. & Prof. Code § 17200 *et seq.*, which provides a cause of action against "any unlawful, unfair or fraudulent business act or practice." App., *infra*, 26a. Amgen alleged that Sandoz committed "unlawful" acts for purposes of the UCL by violating the BPCIA. App., *infra*, 9a. Specifically, Amgen alleged that Sandoz violated the BPCIA (1) by not providing Amgen its application within 20 days of FDA's acceptance of Sandoz's application and (2) by giving an allegedly premature, ineffective notice of commercial marketing before FDA approval. *Ibid.*

Second, Amgen brought a state law claim for conversion, alleging that Sandoz wrongfully used Amgen's approved license for Neupogen®. *Ibid.*

Third, expressly invoking the recourse provided by the BPCIA, 42 U.S.C. § 262(*l*)(9)(C), Amgen brought a claim for artificial infringement of Amgen's U.S. Patent No. 6,162,427 ("'427 patent"), which claims a method of treating a patient using filgrastim. App., *infra*, 9a. Amgen, however, did not seek (and still has not sought) an injunction based on purported patent infringement.

Sandoz counterclaimed, seeking declaratory judgments concerning the correct interpretation of the BPCIA and for non-infringement and invalidity of the '427 patent. *Ibid.*

b. On March 6, 2015, the FDA approved Sandoz's biosimilar filgrastim product Zarxio®, the first biosimilar approved under the BPCIA. App., *infra*, 8a-9a. Although Sandoz "maintained that it gave an operative notice of commercial marketing in July 2014"—the day after filing its biosimilar application, *see supra* p. 12—Sandoz "nevertheless gave a 'further notice of commercial marketing' to Amgen on the date of FDA approval." App., *infra*, 9a.

c. On March 19, 2015, the district court denied Amgen's motions for judgment on the pleadings and for a preliminary injunction and granted Sandoz's motion for judgment on Amgen's state law claims and Sandoz's BPCIA counterclaims. App., *infra*, 56a-84a. The court concluded that it was lawful for Sandoz not to provide Amgen its biosimilar application within 20 days of acceptance by the FDA. App., *infra*, 68a-73a.

The district court also concluded that it was lawful for Sandoz to provide its 180-day notice of commercial marketing before FDA approval, meaning that Sandoz's July 2014 notice was effective. App., *infra*, 73a-76a. The court rejected Amgen's argument that the word "licensed" in the notice provision "means an applicant may not give the required 180-day notice to the reference product sponsor until *after* the FDA has granted approval of biosimilarity—resulting in a mandatory 180-day post-FDA approval waiting period prior to biosimilar market entry." App., *infra*, 74a. The district court explained that "licensed" in the provision refers only to the fact that the product must be licensed before marketing and not to "the appropriate time for notice." App., *infra*, 75a. The court further explained that "[e]ven more problematic with Amgen's reading" is that it would "tack an unconditional extra six months of market exclusivity onto the twelve years reference product sponsors already enjoy under 42 U.S.C. § 262(k)(7)(A)." App., *infra*, 75a-76a.

d. The district court entered final judgment under Federal Rule of Civil Procedure 54(b) on Amgen's state law claims and Sandoz's BPCIA counterclaims. App., *infra*, 11a. The court granted the parties' joint request to stay all other proceedings, including Amgen's patent infringement claim and Sandoz's patent counterclaims. *Ibid.*

3. Proceedings in the Federal Circuit

a. On May 5, 2015, the Federal Circuit issued an injunction pending appeal, precluding Sandoz from marketing, selling, offering for sale, or importing into the United States its FDA-approved Zarxio® product. App., *infra*, 31a; CAFC Dkt. No. 105.

b. On July 21, 2015, a fractured Federal Circuit panel affirmed the dismissal of Amgen's state law claims for unfair competition and conversion, vacated the judgment on Sandoz's counterclaims, and remanded. App., *infra*, 1a-55a. The court also extended the injunction pending appeal through September 2, 2015—180 days from when the FDA approved Sandoz's filgrastim and Sandoz provided its second notice of commercial marketing. App., *infra*, 31a.

Disclosure of the application. A majority of the panel (Judge Lourie joined by Judge Chen) agreed with Sandoz that, considering the statute as a whole, the BPCIA "explicitly contemplates" that an applicant might not take the first step in the information exchange process: disclosing its application to the sponsor under subsection (*l*)(2)(A). App., *infra*, 15a. As the court explained, the BPCIA "specifically sets forth the consequence for such failure: the [sponsor] may bring an infringement action under 42 U.S.C. § 262(*l*)(9)(C) and 35 U.S.C. § 271(e)(2)(C)(ii)." *Ibid.* Both provisions "are premised on a claim of patent infringement, and the BPCIA does not specify any non-patent-based remedies for a failure to comply with paragraph (*l*)(2)(A)." App., *infra*, 17a. "Because

Sandoz took a path expressly contemplated by the BPCIA," the court held, "it did not violate the BPCIA by not disclosing its [application] and the manufacturing information by the statutory deadline." App., *infra*, 18a. Judge Newman dissented from this part of the decision. App., *infra*, 35a-42a (Newman, J., dissenting).

Notice of commercial marketing. The Federal Circuit interpreted the BPCIA's "[n]otice of commercial marketing" provision to mean that the "applicant may only give effective notice of commercial marketing *after* the FDA has licensed its product." App., *infra*, 20a (emphasis added). As noted, the provision states that the applicant "shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k)." 42 U.S.C. § 262(*l*)(8)(A). The Federal Circuit read the phrase "licensed under subsection (k)" to require that notice "be given only after the product is licensed by the FDA," rather than as simply referring to the fact that the biological product will be licensed before marketing. App., *infra*, 20a. Based on this reading of the statute, the court concluded that Sandoz's July 2014 notice of commercial marketing was "premature and ineffective" and that Sandoz's March 2015 notice "serves as the operative and effective notice of commercial marketing in this case." App., *infra*, 23a.

Injunction. In contrast with the majority's conclusion that the BPCIA provided the exclusive consequence for not disclosing a biosimilar application

under subsection (*l*)(2)(A), a second majority (Judge Lourie joined by Judge Newman) did "not find any provision in the BPCIA that contemplates, or specifies the consequence for, noncompliance with" the notice of commercial marketing provision in a case, like this one, where the patent exchange process did not take place. App., *infra*, 24a-25a. The majority acknowledged that subsection (*l*)(9)(B) expressly provides that if a biosimilar applicant does not provide its notice of commercial marketing, "'the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of Title 28, for a declaration of infringement, validity, or enforceability of any patent included in the list'" prepared by the sponsor early in the patent exchange process. App., *infra*, 24a-25a (quoting 42 U.S.C. § 262(*l*)(9)(B)) (emphasis by CAFC omitted).

The majority concluded, however, that this consequence "does not apply" where, as here, the biosimilar applicant did not initiate the patent exchange process because the referenced "list" of patents that could be the basis of a declaratory judgment action does not exist. App., *infra*, 25a. The majority further concluded that the notice provision is a "mandatory," "standalone" provision that must be complied with, regardless of whether the applicant has disclosed its application under subsection (*l*)(2)(A). App., *infra*, 25a-26a. It then ruled (without specifying any source of its remedial authority to do so) that "Sandoz therefore may not market Zarxio before 180 days from March 6, 2015, *i.e.*, September 2, 2015."

App., *infra*, 26a. And the majority fashioned its own injunctive remedy: "In light of what we have decided concerning the proper interpretation of the contested provisions of the BPCIA, we accordingly order that the injunction pending appeal be extended through September 2, 2015"—that is, 180 days from Sandoz's post-approval notice of commercial marketing. App., *infra*, 31a.

Judge Chen dissented from this portion of the decision. App., *infra*, 42a-55a (Chen, J., dissenting). He criticized the majority's reading of the notice provision as giving the reference product sponsor "an extra-statutory exclusivity windfall." App., *infra*, 44a (Chen, J., dissenting). Judge Chen did not "view (*l*)(8)(A) as a 'standalone provision' that provides, implicitly, the [reference product sponsor] a 180-day injunction beyond the express twelve-year statutory exclusivity period." App., *infra*, 43a-44a (Chen, J., dissenting). He noted that Congress knew how to "create a 180-day automatic stay," if it wished to do so. App., *infra*, 52a-53a (Chen, J., dissenting). For example, Congress "could have tied FDA approval to the notice provision" by providing that FDA approval cannot be effective until 180 days after notice is given. App., *infra*, 53a (Chen, J., dissenting).

Judge Chen explained that, "when reading (*l*)(8) in the context of subsection (*l*) as a whole, it becomes clear that (*l*)(8) is simply part and parcel of the integrated litigation management process contemplated in (*l*)(2)-(*l*)(7)." App., *infra*, 43a (Chen, J., dissenting). He would have held that, "when, as here, the

[biosimilar] applicant fails to comply with (*l*)(2), the provisions in (*l*)(3)-(*l*)(8) cease to matter." *Ibid.* Moreover, recognizing that subsection (*l*) "concerns one thing: patent litigation," App., *infra*, 45a (Chen, J., dissenting), Judge Chen would have held that the BPCIA provides the exclusive consequence for failure to provide 180 days' notice: the reference product sponsor may file a declaratory judgment suit for patent infringement. App., *infra*, 51a-52a (Chen, J., dissenting).

State law claims. The first majority (with Judge Newman dissenting) affirmed the dismissal of Amgen's UCL claim with respect to Sandoz's failure to provide its biosimilar application on the ground that such failure "did not violate the BPCIA" and that the Patent Act "provides 'the only remedies which may be granted by a court' for the alleged violation." App., *infra*, 27a (quoting 35 U.S.C. § 271(e)(4)). The majority found "moot" Amgen's "appeal from the dismissal of its unfair competition claim based on the alleged violation of" the notice of commercial marketing provision on the ground that the court of appeals "will extend the injunction pending appeal through September 2, 2015." App., *infra*, 27a-28a. The court also affirmed dismissal of Amgen's conversion claim because, among other reasons, Amgen "failed to show a 'wrongful act'" on Sandoz's part. App., *infra*, 28a-29a.

d. Sandoz launched its biosimilar filgrastim product Zarxio® in the United States on September 3, 2015.

e. Both Sandoz and Amgen filed petitions for rehearing en banc. App., *infra*, 85a-86a. Sandoz's petition was supported by multiple amici who stressed the importance of this issue: the Biosimilars Council (CAFC Dkt. No. 139), Hospira, Inc., Celltrion Healthcare Co., Ltd., and Celltrion, Inc. (CAFC Dkt. No. 140); and Mylan Inc. (CAFC Dkt. No. 150). The Federal Circuit denied en banc review. App., *infra*, 85a-86a.

f. The Federal Circuit remanded to the district court, which lifted the stay on Amgen's patent claims and Sandoz's patent infringement counterclaim. Amgen still has sought no patent-based injunction.

REASONS FOR GRANTING THE PETITION

THE FEDERAL CIRCUIT'S "EXTRA-STATUTORY EXCLUSIVITY WINDFALL" IS CONTRARY TO THE STATUTE'S TEXT AND PURPOSE AS WELL AS THIS COURT'S PRECEDENTS

This Court should grant review because the Federal Circuit has interpreted the BPCIA's notice of commercial marketing provision so as to grant a 180-day "exclusivity windfall" to reference product sponsors. The Federal Circuit's erroneous interpretation will delay the availability of all biosimilars for 180 days more than Congress intended—even if the sponsor has no valid patent claims and even if the sponsor already has had the opportunity to pursue any valid claims. The text and purpose of Section 262(*l*)(8)(A) call for notice 180 days *before* commercial marketing; nothing requires that the applicant wait until *after* FDA approval to provide that notice of commercial marketing. Yet the Federal Circuit read that limitation into the statute. It compounded its error by disconnecting the notice provision from the BPCIA's patent resolution regime and creating an extra-textual injunctive remedy. The Federal Circuit's ruling is contrary to the statute's plain text and purpose and to this Court's precedents. No other court of appeals will review this question; the Federal Circuit has bound the nation. This Court's review of this important federal question is needed now. *See* Sup. Ct. R. 10(c).

A. The Federal Circuit's Post-Approval Limitation Is Contrary To The Text And Purpose Of The Notice Of Commercial Marketing Provision And Conflicts With This Court's Decisions

1. The Federal Circuit's interpretation of Section 262(l)(8)(A) conflicts with the statutory text and upends the provision's purpose

Section 262(*l*)(8)(A) is entitled "Notice of commercial marketing." 42 U.S.C. § 262(*l*)(8)(A). By its plain terms, subsection (*l*)(8)(A) provides only for the applicant to give notice to the product sponsor "180 days before the date of the first commercial marketing" of its biosimilar. *Ibid.* So long as the notice is provided 180 days before the applicant brings its competing biosimilar to market, the plain language of this provision is satisfied. Nothing in the statutory text requires the applicant to wait until after FDA approval, then provide notice that it intends to market, and then wait six months more.

Indeed, Congress knew how to require that an action be both "after" one event and "before" another. It did that in the very next subsection, (*l*)(8)(B): "*After* receiving the notice under subparagraph (A) and *before* such date of the first commercial marketing * * * ." *Id.* § 262(*l*)(8)(B) (emphasis added). Comparable language is markedly absent from subsection (*l*)(8)(A). Congress easily could have provided that notice should be given "*after* receiving FDA approval and 180 days *before* the date of the first commercial marketing"; it did not.

Despite the lack of a requirement in the statute's text that the notice of commercial marketing must be given after FDA approval, the Federal Circuit found such a requirement in the adjective "licensed" in the phrase "the biological product licensed under subsection (k)." *Id.* § 262(*l*)(8)(A). But that phrase just identifies the product whose commercial marketing is relevant to measuring the 180-day period. As the district court explained (App., *infra*, 75a), Congress's use of "licensed" reflects the fact that, by the time the biosimilar product is commercially marketed, it will be "licensed under subsection (k)." *See* 42 U.S.C. § 262(a)(1)(A); *see also* App., *infra*, 75a ("'Before' modifies 'first commercial marketing'; 'licensed' refers only to 'biological product'—not the appropriate time for notice.").

The provision's use of "licensed under subsection (k)" also is consistent with Congress's use of the phrase elsewhere simply to distinguish between the two different ways that a biologic product can be licensed: under subsection (k) as opposed to under subsection (a). For example, the BPCIA provides that a biologic cannot be marketed unless "a biologics license under this subsection [i.e., subsection (a)] or subsection (k) is in effect for the biological product." 42 U.S.C. § 262(a)(1)(A). The statute also defines a "reference product" as a "biological product licensed under subsection (a) against which a biological product is evaluated in an application submitted under subsection (k)." *Id.* § 262(i)(4).

In nevertheless finding a temporal requirement buried in "licensed," the Federal Circuit ignored this Court's admonition that Congress does not "hide elephants in mouseholes." *Whitman v. Am. Trucking Ass'ns, Inc.*, 531 U.S. 457, 468 (2001). As the district court aptly observed in rejecting Amgen's argument, "[h]ad Congress intended to make the exclusivity period twelve and one-half years, it could not have chosen a more convoluted method of doing so." App., *infra*, 76a. If Congress had wished to preclude notice until after FDA approval, it would have said so directly.

Other textual language reinforces that the Federal Circuit's interpretation is wrong. The notice of commercial marketing provision expressly authorizes a "subsection (k) *applicant*" to provide the notice. 42 U.S.C. § 262(*l*)(8)(A) (emphasis added). The provision thus contemplates that the notifying party needs only to have requested FDA approval, not to have received it. Elsewhere in the statute, Congress refers to parties holding approved applications as "holders." *See id.* § 262(m)(3) (referring to "the holder of an approved application"). If Congress had meant to require approval before notice, it would have used consistent language here and called the notifying party "the holder of an approved application."

The Federal Circuit's interpretation of Section 262(*l*)(8)(A) also makes little sense, as it renders the "notice" pointless. The provision's purpose is to "provide *notice* to the reference product sponsor" at least 180 days before the applicant intends to market

its biosimilar, *id.* § 262(*l*)(8)(A) (emphasis added), so that the sponsor can sue on any patent claims it has not yet asserted. The Federal Circuit recognized this was the provision's purpose. *See* App., *infra*, 7a (observing that the notice "allows the [sponsor] a period of time to seek a preliminary injunction based on patents"). But that purpose is better served before approval. Indeed, there is no need for special notice after approval: FDA licensure of a biosimilar is a public act. *See, e.g.*, Press Release, FDA, *FDA Approves First Biosimilar Product Zarxio* (Mar. 6, 2015) (announcing approval of Sandoz's application for filgrastim).[8]

The Federal Circuit thought that "[r]equiring that a product be licensed before notice of commercial marketing ensures the existence of a fully crystallized controversy regarding the need for injunctive relief." App., *infra*, 21a. Whatever the merits of that policy-based rationale, there is no basis for it in the text of the statute. The BPCIA's amendments to the patent laws establish a crystallized patent dispute upon the filing of a biosimilar application with the FDA. 42 U.S.C. § 262(*l*)(2)(A). In the artificial infringement actions created by the statute, it is the application that "circumscribes and dominates the assessment of potential infringement." *Sandoz Inc. v. Amgen Inc.*, 773 F.3d 1274, 1281 (Fed. Cir. 2014). But if, as the Federal Circuit believed, notice had to await licensure,

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[8] http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm436648.

there would be no need for the artificial infringement suits that the notice allows. After licensure, the alleged actual infringement would be sufficiently imminent that the sponsor or applicant could simply file a declaratory judgment suit and seek a preliminary injunction under the ordinary infringement provisions of 35 U.S.C. § 271(a) and/or (g). *See MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007); *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1570-71 (Fed. Cir. 1997).

2. *The Federal Circuit's ruling disrupts the careful balance struck by Congress by delaying the launch of every biosimilar product by six months*

a. The Federal Circuit's ruling disrupts the careful balance struck by Congress. In the BPCIA, Congress sought to facilitate prompt access to cost-saving biosimilars while promoting innovation in biologics. BPCIA § 7001(b), 124 Stat. at 804 (reproduced at App., *infra*, 87a). To speed competing biosimilars to market, Congress allowed the FDA to approve biosimilar products by relying in part on previous approvals of reference products. App., *infra*, 5a-6a; 42 U.S.C. § 262(i)(2), (k). In exchange, Congress granted reference product sponsors up to 12 years of exclusivity from competition from biosimilars—regardless of whether the sponsor has any valid patent claims.

Specifically, in a section titled "Exclusivity for reference product," Congress provided that the FDA's

"[a]pproval of [a biosimilar] application under this subsection may not be made effective by the Secretary until the date that is 12 years after the date on which the reference product was first licensed." 42 U.S.C. § 262(k)(7)(A). Under the clear terms of this provision, once the expressly granted exclusivity period has run, the FDA's approval is "made effective," and the biosimilar applicant should be able to market immediately, absent the successful assertion by the sponsor of any valid patent claims.

Not so under the Federal Circuit's ruling: the applicant must first obtain approval from the FDA, then give notice to the sponsor (of the self-evident fact) that it intends to market its now-approved biosimilar, and finally wait 180 days before marketing. App., *infra*, 20a. As Judge Chen explained in dissent, the majority's reading of the notice of commercial marketing provision gives the sponsor an "extra-statutory exclusivity windfall"—"a 180-day injunction beyond the express twelve-year statutory exclusivity period." App., *infra*, 43a-44a (Chen, J., dissenting). But as Judge Chen observed, "[i]f Congress intended to create a 180-day automatic stay it understood how to do so." App., *infra*, 52a-53a (Chen, J., dissenting). Indeed, Congress expressly extended the exclusivity period to "12 years and 6 months rather than 12 years" for sponsors that successfully complete pediatric studies. 42 U.S.C. § 262(m)(2)(A).

Congress also "could have tied FDA approval to the notice provision" by providing that FDA approval cannot be effective until 180 days after notice is

given. App., *infra*, 53a (Chen, J., dissenting). Congress did not do so. Instead, it expressly directed that the approval be "made effective" upon expiration of the statutorily defined exclusivity period. 42 U.S.C. § 262(k)(7)(A). Nevertheless, the Federal Circuit radically transformed this mere notice provision into an automatic six-month bar against the marketing of an already-approved biosimilar. In doing so, it effectively stripped the FDA of its authority to make its biosimilar approvals "effective" at the end of the statutorily prescribed exclusivity period. *Ibid.*

The Federal Circuit attempted to downplay the significance of its holding by suggesting that the extra 180 days of exclusivity "will not likely be the usual case, as [applications] will often be filed during the 12-year exclusivity period for other products." App., *infra*, 22a. That does not follow. The Federal Circuit's holding hinges on the "licensed" product language in subsection (*l*)(8)(A). Until the 12 years of statutory exclusivity has run, the biosimilar will not be "licensed." *See* 42 U.S.C. § 262(k)(7)(A); Draft Guidance, FDA, *Guidance for Industry: Reference Product Exclusivity for Biological Products Filed Under Section 351(a) of the PHS Act* 2 (Aug. 2014).[9] Under the Federal Circuit's decision, only at that point can the applicant provide an effective notice of commercial marketing. App., *infra*, 20a. As a result,

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[9] http://www.fda.gov/downloads/drugs/guidancecompliance regulatoryinformation/guidances/ucm407844.pdf.

if the Federal Circuit's decision is left standing, *all* biosimilars will be delayed by 180 days.

b. While adding six months of exclusivity found nowhere in the statute, the Federal Circuit's ruling also frustrates the BPCIA's early patent resolution regime. Congress sought to have patent disputes resolved early—preferably before approval—so that biosimilars can be available to patients as soon as possible. To that end, Congress created new artificial infringement actions to allow patent suits to be brought before any actual infringement has occurred, long before FDA approval. 35 U.S.C. § 271(e)(2)(C).

But the Federal Circuit's ruling will mean that, in *every* situation where the parties participate in the patent exchange process, any not yet litigated patents cannot even *begin* to be litigated until after FDA approval. That is because, when the applicant and the sponsor are engaging (or have engaged) in the patent exchange process, only agreed-upon patents may be litigated before the notice of commercial marketing is given. Any other patents in dispute are subject to a stay on artificial infringement declaratory judgment suits. The notice lifts that stay. 42 U.S.C. § 262(*l*)(9)(A) (lifting stay on patents described in § 262(*l*)(8)(B)(i) and (ii)). Provision of the notice also allows the sponsor (if and when it chooses) to ask for preliminary injunctive relief. *Id.* § 262(*l*)(8)(B). If, as the Federal Circuit held, notice cannot be given until after FDA approval, any remaining litigation cannot even be initiated until after approval. Nothing in the statute supports that result, which is

entirely inconsistent with a statute structured to maximize the chance that any patent disputes will be resolved *before* FDA approval.

3. The Federal Circuit erroneously divorced the notice of commercial marketing provision from the patent resolution scheme and created an extra-textual injunctive remedy to enforce it

a. The Federal Circuit's incorrect reading of the notice of commercial marketing provision also caused it to transform the notice provision into a stand-alone requirement unconnected from the BPCIA's patent resolution provisions and to distort the BPCIA's patent-oriented remedial scheme. After concluding that the 180-day notice could not be given until after FDA approval, the majority disregarded the remedies provided by the BPCIA and instead created its own extra-textual remedy to enforce its interpretation: a private right of action for an automatic injunction. That judicially created injunction bars the marketing of the already approved biosimilar until 180 days after the post-approval notice—without regard to whether the sponsor could show any valid patent rights or any irreparable harm. That ruling conflicts with the BPCIA and this Court's precedents tightly circumscribing courts' ability to infer rights of action not expressly created by Congress.

This Court has made clear that courts are not free to fashion their own remedies. *See Alexander v. Sandoval*, 532 U.S. 275, 286-87 (2001). "Like substantive federal law itself, private rights of action to

enforce federal law must be created by Congress." *Id.* at 286. "The judicial task is to interpret the statute Congress has passed to determine whether it displays an intent to create not just a private right but also a private remedy." *Ibid.* "Without it, a cause of action does not exist and courts may not create one, no matter how desirable that might be as a policy matter, or how compatible with the statute." *Id.* at 286-87.

As this Court has emphasized, where "a statute expressly provides a remedy, courts must be especially reluctant to provide additional remedies." *Karahalios v. Nat'l Fed'n of Fed. Emps.*, 489 U.S. 527, 533 (1989). Other Circuits follow that rule: "to imply injunctive authority" in a statute that does not expressly provide it "would exceed what was contemplated by the executive and legislative branches in enacting" the statute and "arrogate to [courts] powers rightfully retained by those two branches of government." *Colorado v. Idarado Mining Co.*, 916 F.2d 1486, 1497-98 (10th Cir. 1990); *see United States v. EME Homer City Generation, L.P.*, 727 F.3d 274, 291-96 (3d Cir. 2013); *Wheeling-Pittsburgh Steel Corp. v. Mitsui & Co.*, 221 F.3d 924 (6th Cir. 2000).

In conflict with those decisions, the Federal Circuit fashioned an injunctive remedy not contemplated by the statute and layered it on top of the remedies the statute does provide. Despite affirming dismissal of the only causes of action on appeal (two state law claims) (App., *infra*, 29a), the majority created a private right of action for an automatic

injunction to specifically enforce its reading of the notice of commercial marketing provision. App., *infra*, 25a-26a, 31a. But the BPCIA provides neither that right nor that remedy.

With the exception of the confidentiality provision—which is not applicable here—Congress did not make the provisions in Section 262(*l*) specifically enforceable. In other words, it created no cause of action for either the applicant or the sponsor to obtain an injunction to compel the other party to comply with any of the provisions in that subsection. In contrast, Congress expressly made the confidentiality provision enforceable by an injunction—and that provision proves that Congress knew how to provide an injunctive remedy when it wished to do so. *See* 42 U.S.C. § 262(*l*)(1)(H); *see also Touche Ross & Co. v. Redington*, 442 U.S. 560, 571-72 (1979) (where Congress provides a particular type of remedy in one portion of a statute but not another, that choice must be given effect).

Instead of providing for judicial enforcement of subsection (*l*)'s provisions via injunctions, the BPCIA provides patent-based remedies. As Judge Chen correctly observed, "Entitled 'Patents,' § 262(*l*) of the BPCIA concerns one thing: patent litigation." App., *infra*, at 45a (Chen, J., dissenting). The actions or inactions of the applicant and sponsor under the Section 262(*l*) provisions all lead to the same result: a possible pre-approval artificial infringement suit. 35 U.S.C. § 271(e)(2)(C), (4), (6); 42 U.S.C. § 262(*l*)(6), (9)(A)-(B). Moreover, the statute expressly provides

that the patent-based remedies "are the *only remedies* which may be granted by a court" for the artificial acts of infringement created by the BPCIA. 35 U.S.C. § 271(e)(4) (emphasis added); *see ibid.* (exception only for attorneys' fees). The BPCIA's express injunctive remedies against marketing therefore all require a showing of possible infringement of a valid patent, as well as the traditional factors for an injunction. *Id.* § 271(e)(2)(C), (4), (6); *see eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 394 (2006).

As particularly relevant here, and consistent with the BPCIA's overall patent-based remedial approach, the remedy Congress provided for the failure to provide the notice of commercial marketing under subsection (*l*)(8)(A) is the ability to bring an artificial infringement suit. Specifically, when an applicant engages in the patent exchange process, yet does not provide notice of commercial marketing: "the reference product sponsor, but not the subsection (k) applicant, may bring" an action for a "declaration of infringement, validity, or enforceability" with respect to certain patents identified earlier in the patent exchange process. 42 U.S.C. § 262(*l*)(9)(B) (cross-referencing, *inter alia*, 42 U.S.C. § 262(*l*)(8)(A)).

Although the majority acknowledged that express remedy, it brushed it aside, concluding "it does not apply in this case" because Sandoz did not engage in the patent exchange process. App., *infra*, 25a. But as Judge Chen explained in dissent, the notice provision is not a stand-alone requirement; "it is part and parcel to, and contingent upon, the preceding steps in

the (*l*)(2)-(*l*)(8) litigation management regime." App., *infra*, 50a (Chen, J., dissenting). When there has been no initiation of the patent exchange process, "compliance with (*l*)(8)(A) [is] unnecessary." App., *infra*, 52a (Chen, J., dissenting). Moreover, in such a circumstance, a sponsor "does not need the remedy in (*l*)(9)(B) because (*l*)(9)(C) and § 271(e)(2)(C)(ii) already grant the right to file, immediately, an unrestricted patent infringement action," as Amgen has done here. App., *infra*, 51a (Chen, J., dissenting). "[T]he absence of such a remedial provision in (*l*)(9)(B) *confirms* that Congress deemed any additional remedy to be unnecessary." *Ibid.* The sponsor already "possesses the statutory right to seek a preliminary injunction for any of its patents." *Ibid.*

Even where parties have engaged in the patent exchange process, the Federal Circuit's decision in this case has led to extra-textual injunctive relief. At least one district court applying the decision below already has enjoined a biosimilar from marketing until 180 days after it notifies the sponsor of FDA approval, even though the applicant provided the sponsor its application under subsection (*l*)(2). *See Amgen Inc. v. Apotex Inc.*, No. 15-61631, slip op. at 2-8 (S.D. Fla. Dec. 9, 2015), appeal docketed, No. 16-1308 (Fed. Cir. Dec. 11, 2015).

In any event, the majority's dissatisfaction with the remedies afforded by Congress did not give it license to fashion its own. That exercise in judicial creativity directly contravenes this Court's precedents. *See, e.g.*, *Sandoval*, 532 U.S. at 286-87;

Karahalios, 489 U.S. at 533. Unless reviewed and reversed, that ruling will provide (and already is providing) an automatic 180-day post-approval injunction to every sponsor against every biosimilar product, even where the sponsor has no valid patent claims.

Finally, the injunction granted by the Federal Circuit conflicted with this Court's precedent in an additional way. The majority enjoined Sandoz without regard to traditional equitable factors, despite the district court's undisturbed findings that Amgen would suffer no irreparable harm. *See* App., *infra*, 82a-83a; D. Ct. Dkt. No. 129. That approach conflicts with this Court's decision in *eBay*, which emphasized that the Court "has consistently rejected invitations to replace traditional equitable considerations with a rule that an injunction automatically follows a determination" of a statutory violation. 547 U.S. at 392-93.

b. Although Sandoz has now launched its biosimilar product, a live controversy remains concerning the notice of commercial marketing provision. This issue fits within the established exception to mootness for disputes capable of repetition, yet evading review. *See FEC v. Wis. Right to Life, Inc.*, 551 U.S. 449, 462-64 (2007). Sandoz will be a repeat biosimilar applicant; Sandoz is the global market leader for biosimilars and has a pipeline of biosimilars across various stages of development, including five programs that are in late-stage clinical trials or for which an FDA application already has

been submitted.[10] Sandoz therefore has a "reasonable expectation" that it will again be subject to the notice of commercial marketing provision. *FEC*, 551 U.S. at 463. When that happens, the 180-day period will again be too short for the issue to be "fully litigated prior to cessation or expiration" in a future case. *Id.* at 462 (citation omitted). This Court's immediate review is needed now.

B. This Court's Review Is Urgently Needed Because The Federal Circuit's Ruling Is Delaying The Availability Of All Biosimilars And Will Continue To Do So Until This Court Corrects The Circuit's Interpretation

If the Federal Circuit's incorrect ruling is not reversed, patients will have to wait six more months than Congress intended for *every* biosimilar—even though the FDA already has approved it and even if the sponsor has no valid patent rights to enforce or already has had the opportunity to assert any patent claims. As the Biosimilars Council explained in its amicus brief supporting en banc review, the Federal Circuit's "automatic, extra-statutory delay, if left uncorrected, would broadly undercut Congress's goal of greater competition in biologics markets and dramatically reduce savings to the U.S. healthcare system from biosimilars." CAFC Dkt. No. 139 at 2. This is an issue of critical importance to patients, the

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[10] Sandoz: Several Biosimilars in Late-Stage Clinical Trials, http://www.sandoz-biosimilars.com/en/clinicaltrials/sandoz-clinical-trials.shtml.

pharmaceutical industry, and purchasers, including taxpayers (who bear the cost of biologics through Medicare and Medicaid). Given the importance of the public and private interests at stake, this Court's immediate review is warranted.

In 2013, biologics accounted for approximately $80 billion in spending in the United States—approximately 25% of all pharmaceutical spending. FTC, *Public Workshop: Follow-On Biologics: Impact of Recent Legislative and Regulatory Naming Proposals on Competition*, 78 Fed. Reg. 68,840, 68,841 (Nov. 15, 2013).[11] Biologics are "among the most important pharmaceutical products in the United States," and they "comprise the fastest growing sector within pharmaceuticals." *Id.* at 68,840. As Mylan explained in its amicus brief supporting rehearing en banc, biologics cost on average $45 per patient per day (compared with $2 per day for traditional, chemically synthesized drugs). CAFC Dkt. No. 150 at 10. The cost of biologics regularly runs into the tens or hundreds of thousands of dollars per patient per year. Robert J. Shapiro, et al., *The Potential American Market for Generic Biological Treatments and the Associated Cost Savings* 4 (Feb. 2008);[12] *see also* CBO, Pub. No. 4043, *Effects of Using Generic Drugs on Medicare's Drug Spending* 20 (Sept. 2010) ("[Biologic]

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[11] https://www.ftc.gov/sites/default/files/documents/federal_register_notices/2013/11/131115biologicsfrn.pdf.

[12] http://www.sonecon.com/docs/studies/0208_GenericBiologicsStudy.pdf.

drugs can be particularly expensive, with prices reaching tens of thousands of dollars per patient each year.").[13]

Congress enacted the BPCIA to tackle these enormous costs by speeding biosimilars to market, while still preserving incentives for innovation. As the FDA Commissioner explained, the introduction of biosimilars would "increase competition and create substantial savings for patients, healthcare providers, and insurers." Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations for Fiscal Year 2014, Hearings Before a Subcomm. of the Comm. on Appropriations on H.R. 2410/S. 1244, 113th Cong. 9 (2013) (statements of Dr. Margaret A. Hamburg). The CBO estimated that efficient introduction of biosimilars "would reduce total expenditures on biologics in the United States * * * by about $25 billion over the 2009-2018 period." CBO Cost Estimate, *supra*, at 1.

These enormous savings would result from price competition. The CBO estimates "that prices for biosimilars would ultimately be about 40 percent lower than prices of the original drugs * * * ." CBO, Pub. No. 4043, *supra*, at 21. And, according to the Congressional Research Service ("CRS"), the price of the reference product is expected to decrease by as much as 47% within five years of the launch of a

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[13] https://www.cbo.gov/sites/default/files/111th-congress-2009-2010/reports/09-15-prescriptiondrugs.pdf.

competing biosimilar. CRS, John R. Thomas, *Follow-On Biologics: The Law and Intellectual Property Issues*, R41483, at 17-18 (2014).[14]

An FTC report concluded that this price competition is "likely to lead to an expanded market and greater consumer access," as more patients can afford the lower-priced drugs. *See* FTC Report, *supra*, at 23. Patients taking biologics often have enormous out-of-pocket costs because insurance plans typically treat biologics as "specialty drugs," with coinsurance rates of 20% to 35%. Andrew W. Mulcahy, Zachary Predmore & Soeren Mattke, RAND Corp., *The Cost Savings Potential of Biosimilar Drugs in the United States* 11 (2014).[15]

These savings will benefit the federal government as well. The CBO estimated that the BPCIA would save the federal government $7 billion in reduced healthcare spending from 2010 to 2019. Elmendorf Letter, *supra*, at Table 5 at 10. Indeed, the BPCIA's savings were among those on which the CBO based its conclusion that the Affordable Care Act would reduce the federal budget deficit. *See id.* at 2.

Congress's goals will be frustrated unless and until this Court intervenes. Despite Judge Chen's forceful dissent, the Federal Circuit refused to rehear this issue en banc. Its fractured panel decision thus

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[14] https://www.fas.org/sgp/crs/misc/R41483.pdf.

[15] https://www.rand.org/content/dam/rand/pubs/perspectives/PE100/PE127/RAND_PE127.pdf.

will bind subsequent panels of the Federal Circuit, all district courts in the country, and the pharmaceutical industry. Indeed, as noted, a district court in Florida already has applied the decision in this case to enjoin the marketing of a different biosimilar, the cancer drug pegfilgrastim. *Amgen*, No. 15-61631, slip op. at 2-8; *see supra* p. 35. Similar injunctions are being sought in district courts in Massachusetts and Delaware as to two additional biosimilars, the rheumatoid-arthritis drug infliximab and the anemia drug epoetin alfa. *See Janssen Biotech, Inc. v. Celltrion Healthcare Co.*, No. 15-10698 (D. Mass. Aug. 24, 2015), ECF No. 72; *Amgen Inc. v. Hospira, Inc.*, No. 15-839 (D. Del. Nov. 6, 2015), ECF No. 11. Epoetin alfa has accounted for the single highest annual drug expenditure by Medicare Part B. Testimony of James Cosgrove, Director, Health Care, GAO, before the House Subcommittee on Health, Committee on Energy and Commerce, at 5 (June 28, 2013).[16]

For all these reasons, this Court's review is urgently needed. The Federal Circuit's decision is now delaying *every* patient's access to *all* biosimilars for at least 180 days after FDA approval. That situation should not be allowed to continue without this Court's plenary review.

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[16] http://www.gao.gov/assets/660/655608.pdf.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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FEBRUARY 16, 2016

APPENDIX A

United States Court of Appeals for the Federal Circuit

AMGEN INC., AMGEN MANUFACTURING LIMITED,
Plaintiffs-Appellants

v.

SANDOZ INC.,
Defendant-Appellee

2015-1499

Appeal from the United States District Court for the Northern District of California in No. 3:14-cv-04741-RS, Judge Richard Seeborg.

Decided: July 21, 2015

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Before NEWMAN, LOURIE, and CHEN, *Circuit Judges*.

Opinion for the court filed by *Circuit Judge* LOURIE.

Opinion concurring in part, dissenting in part filed by *Circuit Judge* NEWMAN.

Opinion dissenting in part filed by *Circuit Judge* CHEN.

LOURIE, *Circuit Judge*.

This appeal presents issues of first impression relating to the Biologics Price Competition and Innovation Act of 2009 ("BPCIA"), Pub. L. No. 111-148, §§ 7001-7003, 124 Stat. 119, 804-21 (2010). Amgen Inc. and Amgen Manufacturing Ltd. (collectively, "Amgen") appeal from the decision of the United States District Court for the Northern District of California (1) dismissing Amgen's state law claims of unfair competition and conversion with prejudice because Sandoz Inc. ("Sandoz") did not violate the information-disclosure and notice-of-commercial-marketing provisions of the BPCIA, respectively codified at 42 U.S.C. § 262(*l*)(2)(A) and (*l*)(8)(A); (2) granting judgment on the pleadings to Sandoz on its counterclaims seeking a declaratory judgment that it correctly interpreted the BPCIA; and (3) denying Amgen's motion for a preliminary injunction based on its state law claims. *Amgen Inc. v. Sandoz Inc.*, No. 14-cv-04741, 2015 WL 1264756 (N.D. Cal. Mar. 19, 2015) ("*Opinion*").

For the reasons stated below, we affirm the dismissal of Amgen's state law claims of unfair competition and conversion, vacate the judgment on Sandoz's counterclaims and direct the district court to enter judgment consistent with our interpretation of the BPCIA, and remand for further proceedings consistent with this opinion.

A. Background

I.

In 2010, as part of the Patient Protection and Affordable Care Act, Congress enacted the BPCIA,[1] which established an abbreviated pathway for regulatory approval of follow-on biological products that are "highly similar" to a previously approved product ("reference product"). Pub. L. No. 111-148, §§ 7001-7003, 124 Stat. 119, 804-21 (2010) (codified as amended at 42 U.S.C. § 262, 35 U.S.C. § 271(e), 28 U.S.C. § 2201(b), 21 U.S.C. § 355 et seq.). Congress established such "a biosimilar pathway balancing innovation and consumer interests." BPCIA, Pub. L. No. 111-148, § 7001(b), 124 Stat. at 804.

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[1] Winston Churchill once described Russia as "a riddle wrapped in a mystery inside an enigma." Winston Churchill, *The Russian Enigma* (BBC radio broadcast Oct. 1, 1939), *available at* http://www.churchill-society-london.org.uk/RusnEnig.html. That is this statute. In these opinions, we do our best to unravel the riddle, solve the mystery, and comprehend the enigma.

The BPCIA has certain similarities in its goals and procedures to the Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Act), Pub. L. No. 98-417, 98 Stat. 1585 (1984), but it has several obvious differences. We note this as a matter of historical interest, but otherwise do not comment on those similarities and differences.

Traditionally, the Food and Drug Administration ("FDA") approves a biological product for commercial marketing by granting a biologics license under 42 U.S.C. § 262(a). An applicant filing a biologics license application ("BLA") typically provides clinical data to demonstrate the safety and efficacy of its product. In contrast, under the abbreviated pathway created by the BPCIA, codified at 42 U.S.C. § 262(k), an applicant filing an abbreviated biologics license application ("aBLA" or "subsection (k) application") instead submits information to demonstrate that its product is "biosimilar" to or "interchangeable" with a previously approved reference product, together with "publicly-available information regarding the [FDA]'s previous determination that the reference product is safe, pure, and potent." 42 U.S.C. § 262(k)(2)-(5); *see also id.* § 262(i). The BPCIA thus permits a biosimilar applicant to rely in part on the approved license of a reference product.

To balance innovation and price competition, Congress enacted the BPCIA to provide a four-year and a twelve-year exclusivity period to a reference product, both beginning on the date of first licensure of the reference product. Specifically, a subsection (k)

application "may not be submitted to the Secretary until the date that is 4 years after the date on which the reference product was first licensed under subsection (a)," *id.* § 262(k)(7)(B), and approval of a subsection (k) application "may not be made effective by the Secretary until the date that is 12 years after the date on which the reference product was first licensed under subsection (a)," *id.* § 262(k)(7)(A). Thus, a sponsor of an approved reference product (the "reference product sponsor" or "RPS") receives up to twelve years of exclusivity against follow-on products, regardless of patent protection.

Moreover, the BPCIA established a patent-dispute-resolution regime by amending Titles 28, 35, and 42 of the United States Code. The BPCIA amended the Patent Act to create an artificial "act of infringement" and to allow infringement suits based on a biosimilar application prior to FDA approval and prior to marketing of the biological product. *See* 35 U.S.C. § 271(e)(2)(C), (e)(4), (e)(6). The BPCIA also established a unique and elaborate process for information exchange between the biosimilar applicant and the RPS to resolve patent disputes. *See* 42 U.S.C. § 262(*l*).

Under that process, codified at 42 U.S.C. § 262(*l*), the biosimilar applicant grants the RPS confidential access to its aBLA and the manufacturing information regarding the biosimilar product no later than 20 days after the FDA accepts its application for review. *Id.* § 262(*l*)(1)-(2). The parties then exchange lists of patents for which they believe a claim of

patent infringement could reasonably be asserted by the RPS, as well as their respective positions on infringement, validity, and enforceability of those patents. *Id.* § 262(*l*)(3). Following that exchange, which could take up to six months, the parties negotiate to formulate a list of patents ("listed patents") that would be the subject of an immediate infringement action, *id.* § 262(*l*)(4)-(5), and the RPS then sues the biosimilar applicant within 30 days, *id.* § 262(*l*)(6). That information exchange and negotiation thus contemplates an immediate infringement action brought by the RPS based only on listed patents.

Subsection 262(*l*) also provides that the applicant give notice of commercial marketing to the RPS at least 180 days prior to commercial marketing of its product licensed under subsection (k), which then allows the RPS a period of time to seek a preliminary injunction based on patents that the parties initially identified during information exchange but were not selected for the immediate infringement action, as well as any newly issued or licensed patents (collectively, "non-listed patents"). *Id.* § 262(*l*)(7)-(8).

Subsection 262(*l*) additionally provides, in paragraph (*l*)(9)(A), that if the applicant discloses the information "required under paragraph (2)(A)," then neither the RPS nor the applicant may bring a declaratory judgment action based on the non-listed patents prior to the date on which the RPS receives the notice of commercial marketing under paragraph (*l*)(8)(A). *Id.* § 262(*l*)(9)(A). Paragraphs (*l*)(9)(B) and

(*l*)(9)(C), however, permit the RPS, but not the applicant, to seek declaratory relief in the event that the applicant fails to comply with certain provisions of subsection (*l*). *Id.* § 262(*l*)(9)(B)-(C).

II.

Amgen has marketed filgrastim under the brand name Neupogen® ("Neupogen") since 1991. In May 2014, Sandoz filed an aBLA, seeking FDA approval of a biosimilar filgrastim product, for which Neupogen is the reference product. On July 7, 2014, Sandoz received notification from the FDA that it had accepted Sandoz's application for review.

On July 8, 2014, Sandoz notified Amgen that it had filed a biosimilar application referencing Neupogen; that it believed that the application would be approved in "Q1/2 of 2015"; and that it intended to launch its biosimilar product immediately upon FDA approval. J.A. 1472. Later in July, in response to Amgen's inquiry, Sandoz confirmed that the FDA had accepted its application for review, but Sandoz informed Amgen that it had "opted not to provide Amgen with Sandoz's biosimilar application within 20 days of the FDA's notification of acceptance" and that Amgen was entitled to sue Sandoz under § 262(*l*)(9)(C). J.A. 1495-96. Sandoz thus did not disclose its aBLA or its product's manufacturing information to Amgen according to § 262(*l*)(2)(A).

Subsequently, on March 6, 2015, the FDA approved Sandoz's aBLA for all approved uses of

Amgen's Neupogen. Although Sandoz has maintained that it gave an operative notice of commercial marketing in July 2014, it nevertheless gave a "further notice of commercial marketing" to Amgen on the date of FDA approval. J.A. 1774. Sandoz intended to launch its filgrastim product under the trade name Zarxio.

III.

In October 2014, Amgen sued Sandoz in the Northern District of California, asserting claims of (1) unfair competition for unlawful business practices under California Business & Professions Code § 17200 et seq. ("UCL"), based on two alleged violations of the BPCIA; (2) conversion for allegedly wrongful use of Amgen's approved license on Neupogen; and (3) infringement of Amgen's U.S. Patent 6,162,427 (the "'427 patent"), which claims a method of using filgrastim. Amgen alleged that Sandoz violated the BPCIA by failing to disclose the required information under § 262(*l*)(2)(A) and by giving a premature, ineffective, notice of commercial marketing under § 262(*l*)(8)(A) before FDA approval of its biosimilar product. Sandoz counterclaimed for a declaratory judgment that it correctly interpreted the BPCIA as permitting its actions, and that the '427 patent was invalid and not infringed.

In January 2015, the parties filed cross-motions for judgment on the pleadings on Amgen's state law claims and Sandoz's counterclaims interpreting the

BPCIA. In February 2015, Amgen also filed a motion for a preliminary injunction based solely on its state law claims to enjoin Sandoz from launching Zarxio after FDA approval. Also in February 2015, through discovery, Amgen obtained access to Sandoz's biosimilar application.

On March 19, 2015, the district court granted partial judgment on the pleadings to Sandoz on its BPCIA counterclaims to the extent that Sandoz's interpretation of the statute is consistent with the court's interpretation. Specifically, the district court concluded that: (1) the BPCIA renders permissible a subsection (k) applicant's decision not to disclose its aBLA and the manufacturing information to the RPS, subject only to the consequences set forth in 42 U.S.C. § 262(*l*)(9)(C); (2) such a decision alone does not offer a basis for the RPS to obtain injunctive relief, restitution, or damages against the applicant; and (3) the applicant may give notice of commercial marketing under § 262(*l*)(8)(A) before FDA approval. *Opinion*, 2015 WL 1264756, at *8, *11.

Based on its interpretation of the BPCIA, the district court then dismissed Amgen's unfair competition and conversion claims with prejudice because it concluded that Sandoz did not violate the BPCIA or act unlawfully. *Id.* at *8-9. The court also denied Amgen's motion for a preliminary injunction based on its state law claims, noting that Amgen "has yet to proceed on its remaining claim for patent infringement." *Id.* at *10.

On the parties' joint motion, the district court entered final judgment as to Amgen's unfair competition and conversion claims and as to Sandoz's BPCIA counterclaims under Rule 54(b) of the Federal Rules of Civil Procedure. The parties' claims and counterclaims relating to infringement, validity, and enforceability of the '427 patent remain pending at the district court.

Amgen timely appealed from the final judgment and from the denial of a preliminary injunction; we have jurisdiction under 28 U.S.C. § 1295(a)(1) and § 1292(a)(1) and (c)(1).

B. Discussion

We apply the procedural law of the regional circuit, here the Ninth Circuit, when reviewing a district court's grant of a motion for judgment on the pleadings. *Merck & Co. v. Hi-Tech Pharmacal Co.*, 482 F.3d 1317, 1320 (Fed. Cir. 2007). The Ninth Circuit reviews the grant of judgment on the pleadings *de novo*, *Peterson v. California*, 604 F.3d 1166, 1169 (9th Cir. 2010), and "accept[s] all material allegations in the complaint as true and construe[s] them in the light most favorable to [the non-moving party]," *Turner v. Cook*, 362 F.3d 1219, 1225 (9th Cir. 2004) (third alteration in original). Issues of statutory interpretation are also reviewed *de novo*. *Qantas Airways Ltd. v. United States*, 62 F.3d 385, 387 (Fed. Cir. 1995).

Because Amgen's state law claims of unfair competition and conversion are premised on the proper interpretation of the BPCIA, we first interpret the relevant provisions of the BPCIA and then consider Amgen's state law claims in light of that interpretation.

I.

We first consider whether the district court erred in concluding that a subsection (k) applicant may elect not to disclose its aBLA and the manufacturing information under 42 U.S.C. § 262(*l*)(2)(A), subject only to the consequences set forth in § 262(*l*)(9)(C). Paragraph (*l*)(2)(A) provides that:

> Not later than 20 days after the Secretary notifies the subsection (k) applicant that the application has been accepted for review, the subsection (k) applicant *shall provide* to the reference product sponsor a copy of the application submitted to the Secretary under subsection (k), and such other information that describes the process or processes used to manufacture the biological product that is the subject of such application . . . .

42 U.S.C. § 262(*l*)(2)(A) (emphasis added). Paragraph (*l*)(9)(C) provides that:

> If a subsection (k) applicant *fails to provide the application and information required under paragraph (2)(A)*, the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of

> Title 28, for a declaration of *infringement, validity, or enforceability of any patent* that claims the biological product or a use of the biological product.

Id. § 262(*l*)(9)(C) (emphases added). Additionally, 35 U.S.C. § 271(e)(2)(C)(ii), as amended by the BPCIA, provides that:

> It shall be an act of infringement to submit . . . if the applicant for the application *fails to provide the application and information required* under section 351(*l*)(2)(A) of such Act, an application seeking approval of a biological product for a patent that could be identified pursuant to section 351(*l*)(3)(A)(i) of such Act . . . .

35 U.S.C. § 271(e)(2)(C)(ii) (emphasis added).[2]

Amgen argues that the language "shall provide" in paragraph (*l*)(2)(A) suggests that the information disclosure is mandatory, not merely permissible. Amgen contends that other provisions of the BPCIA refer to the information as "required" under paragraph (*l*)(2)(A) and also refer to non-disclosure as a failure to comply with the Act. Amgen argues that, by refusing to provide the required information, a subsection (k) applicant unlawfully evades the detection of process patent infringement and avoids an immediate infringement action under § 262(*l*)(6). Amgen

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[2] Section 351(*l*)(2)(A) of the Public Health Act corresponds to 42 U.S.C. § 262(*l*)(2)(A).

also argues that paragraph (*l*)(9)(C) is merely a limitation on declaratory judgment action, not a remedy, let alone the exclusive remedy, for noncompliance with paragraph (*l*)(2)(A).

Sandoz responds that the "shall" provision in paragraph (*l*)(2)(A) is only a condition precedent to engaging in the information-exchange process of paragraphs (*l*)(3) through (*l*)(6), not a mandatory requirement in all circumstances. Sandoz contends that this interpretation is consistent with the use of "shall" in paragraph (*l*)(6), which provides that the RPS "shall" file an infringement suit. Sandoz notes that this use of "shall" cannot mean that the RPS violates the statute if it chooses not to file an infringement suit. Sandoz also responds that, under the BPCIA, if a subsection (k) applicant does not disclose the information under paragraph (*l*)(2)(A), then the sponsor may file an infringement suit under paragraph (*l*)(9)(C) and obtain the information in discovery, which Amgen has done. Sandoz also contends that it did not act unlawfully by taking a path expressly contemplated by Congress and the BPCIA.

We conclude that, read in isolation, the "shall" provision in paragraph (*l*)(2)(A) appears to mean that a subsection (k) applicant is required to disclose its aBLA and manufacturing information to the RPS by the deadline specified in the statute. Indeed, the BPCIA refers to such information as "required" in other provisions. *See* 42 U.S.C. § 262(*l*)(1)(B)(i), (*l*)(9)(A), (*l*)(9)(C); 35 U.S.C. § 271(e)(2)(C)(ii). Particularly, paragraph (*l*)(1)(B)(i) provides that "[w]hen" a

subsection (k) applicant submits an aBLA to the FDA, "such applicant *shall* provide . . . confidential access to the information *required* to be produced pursuant to paragraph (2) and any other information that the subsection (k) applicant determines, in its sole discretion, to be appropriate" (emphases added). Thus, under the plain language of paragraph (*l*)(1)(B)(i), *when* an applicant chooses the abbreviated pathway for regulatory approval of its biosimilar product, it is required to disclose its aBLA and manufacturing information to the RPS no later than 20 days after the FDA's notification of acceptance, but not when the "when" criterion is not met.

Such a reading of "shall" in paragraph (*l*)(2)(A) is supported by the use of "may" in paragraph (*l*)(2)(B), which provides that a subsection (k) applicant "may" provide additional information requested by the RPS by the statutory deadline. Paragraph (*l*)(2)'s use of "shall" in juxtaposition with "may" in the adjacent provision would appear to indicate that "shall" signals a requirement.

However, the "shall" provision in paragraph (*l*)(2)(A) cannot be read in isolation. In other provisions, the BPCIA explicitly contemplates that a subsection (k) applicant might fail to disclose the required information by the statutory deadline. It specifically sets forth the consequence for such failure: the RPS may bring an infringement action under 42 U.S.C. § 262(*l*)(9)(C) and 35 U.S.C. § 271(e)(2)(C)(ii). Those latter provisions indicate that "shall" in paragraph (*l*)(2)(A) does not mean "must." And the BPCIA

has no other provision that grants a procedural right to compel compliance with the disclosure requirement of paragraph (*l*)(2)(A).

Under 35 U.S.C. § 271(e)(2)(C)(ii), filing a subsection (k) application and failing to disclose the required information under paragraph (*l*)(2)(A) is an artificial "act of infringement" of "a patent that could be identified" pursuant to paragraph (*l*)(3)(A)(i). 42 U.S.C. § 262(*l*)(9)(C) further provides that "[i]f a subsection (k) applicant fails to provide the application and information required under paragraph (2)(A)," then the RPS, but not the subsection (k) applicant, may bring a declaratory judgment action on "any patent that claims the biological product or a use of the biological product."[3] As a direct consequence of failing to comply with paragraph (*l*)(2)(A), paragraph (*l*)(9)(C) bars the subsection (k) applicant

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[3] While it is true that 42 U.S.C. § 262(*l*)(9)(C) premises the declaration judgment action on "any patent that *claims the biological product or a use of the biological product*" (emphasis added), which does not appear to include process patents, 35 U.S.C. § 271(e)(2)(C)(ii) does contemplate an infringement action based on "a patent that *could be identified pursuant to [paragraph] (l)(3)(A)(i)*" (emphasis added), which does not exclude process patents. Section 271(e)(2)(C)(ii) allows the RPS to assert process patents, "if the [subsection (k)] applicant . . . fails to provide the application and information" and "the purpose of [the subsection (k)] submission is to obtain approval . . . to engage in the commercial manufacture, use, or sale of a . . . biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent." 35 U.S.C. § 271(e)(2).

from bringing a declaratory judgment action on patents that claim the biological product or its use.

Notably, both 42 U.S.C. § 262(*l*)(9)(C) and 35 U.S.C. § 271(e)(2)(C)(ii) are premised on a claim of patent infringement, and the BPCIA does not specify any non-patent-based remedies for a failure to comply with paragraph (*l*)(2)(A). Once the RPS brings an infringement suit under those two provisions, it can access the required information through discovery.[4]

Importantly, mandating compliance with paragraph (*l*)(2)(A) in all circumstances would render paragraph (*l*)(9)(C) and 35 U.S.C. § 271(e)(2)(C)(ii) superfluous, and statutes are to be interpreted if possible to avoid rendering any provision superfluous. *Marx v. Gen. Revenue Corp.*, 568 U.S. ___, 133 S. Ct. 1166, 1178 (2013) ("[T]he canon against surplusage is strongest when an interpretation would render superfluous another part of the same statutory scheme."); *TRW Inc. v. Andrews*, 534 U.S. 19, 31 (2001) ("It is a cardinal principle of statutory construction that a statute ought, upon the whole, to be so construed that, if it can be prevented, no clause, sentence, or word shall be superfluous, void, or insignificant." (internal quotation marks omitted)).

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[4] In addition, we note the existence of a rebuttable presumption in actions alleging infringement of a process patent under 35 U.S.C. § 271(g) relating to importation of products made abroad by a patented process. *See, e.g., Creative Compounds, LLC v. Starmark Labs.*, 651 F.3d 1303, 1314 (Fed. Cir. 2011) (citing 35 U.S.C. § 295).

Moreover, 35 U.S.C. § 271(e)(4) provides "the *only* remedies which may be granted by a court for an act of infringement described in paragraph (2)" (emphasis added). Under § 271(e)(2)(C)(ii), filing a subsection (k) application and failing to provide the required information under paragraph (*l*)(2)(A) is such an act of infringement. Here, Amgen alleged that Sandoz violated the BPCIA, but the alleged violation is precisely an act of infringement under § 271(e)(2)(C)(ii), for which § 271(e)(4) provides the "only remedies."

We therefore conclude that, even though under paragraph (*l*)(2)(A), when read in isolation, a subsection (k) applicant would be required to disclose its aBLA and the manufacturing information to the RPS by the statutory deadline, we ultimately conclude that when a subsection (k) applicant fails the disclosure requirement, 42 U.S.C. § 262(*l*)(9)(C) and 35 U.S.C. § 271(e) expressly provide the only remedies as those being based on a claim of patent infringement. Because Sandoz took a path expressly contemplated by the BPCIA, it did not violate the BPCIA by not disclosing its aBLA and the manufacturing information by the statutory deadline.

II.

We next consider whether the district court erred in concluding that a subsection (k) applicant may satisfy its obligation to give notice of commercial marketing under 42 U.S.C. § 262(*l*)(8)(A) by doing so before the FDA licenses its product. Paragraph

(*l*)(8)(A) provides that "[t]he subsection (k) applicant *shall* provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product *licensed* under subsection (k)." *Id.* § 262(*l*)(8)(A) (emphases added).

a.

Amgen argues that a subsection (k) applicant may give notice of commercial marketing only after it has a "biological product licensed under subsection (k)," meaning only after the FDA has licensed the biosimilar product. Amgen notes that elsewhere subsection (*l*) refers to the biosimilar product as "the biological product that is the subject of" the application, which supports its interpretation of "licensed" in paragraph (*l*)(8)(A). Amgen explains that giving notice after FDA licensure provides time for the RPS to seek a preliminary injunction and to resolve patent disputes in a timely fashion. Amgen contends that allowing the applicant to give notice before FDA licensure is irreconcilable with the statute's text and purpose.

Sandoz responds that the plain terms of the notice provision are satisfied when an applicant provides notice at least 180 days before it commercially markets its product. According to Sandoz, the word "licensed" only means that, at the time of commercial marketing, the product must be licensed, but it does not limit the timing of the notice, which can be

given before FDA licensure. Sandoz also argues that Amgen's construction of the notice provision would transform it into an automatic, additional, six-month bar against marketing of every licensed biosimilar product, which improperly extends the twelve-year exclusivity period under § 262(k)(7)(A).

We agree with Amgen that, under paragraph (*l*)(8)(A), a subsection (k) applicant may only give effective notice of commercial marketing after the FDA has licensed its product. The statutory language compels such an interpretation. It means that notice, to be effective under this statute, must be given only after the product is licensed by the FDA.

In subsection (*l*), only paragraph (*l*)(8)(A) refers to the product as "the biological product licensed under subsection (k)." In other provisions of subsection (*l*), the statute refers to the product as "the biological product that is the subject of" the application, even when discussing its commercial marketing. *E.g.*, 42 U.S.C. § 262(*l*)(3)(B)(ii)(I), (*l*)(3)(C); *id.* § 262(*l*)(1)(D), (*l*)(2)(A), (*l*)(3)(A)(i), (*l*)(3)(B)(i), (*l*)(7)(B). If Congress intended paragraph (*l*)(8)(A) to permit effective notice before the product is licensed, it would have used the "subject of" language.

While it is true that only a licensed product may be commercially marketed, it does not follow that whenever the future commercial marketing of a yet-to-be licensed product is discussed, it is the "licensed" product. It is not yet "the licensed product." Congress could have used the phrase "the biological product

that is the subject of" the application in paragraph (*l*)(8)(A), as it did in other provisions, but it did not do so. *See, e.g.*, *Russello v. United States*, 464 U.S. 16, 23 (1983).

We believe that Congress intended the notice to follow licensure, at which time the product, its therapeutic uses, and its manufacturing processes are fixed. When a subsection (k) applicant files its aBLA, it likely does not know for certain when, or if, it will obtain FDA licensure. The FDA could request changes to the product during the review process, or it could approve some but not all sought-for uses. Giving notice after FDA licensure, once the scope of the approved license is known and the marketing of the proposed biosimilar product is imminent, allows the RPS to effectively determine whether, and on which patents, to seek a preliminary injunction from the court.

Requiring that a product be licensed before notice of commercial marketing ensures the existence of a fully crystallized controversy regarding the need for injunctive relief. It provides a defined statutory window during which the court and the parties can fairly assess the parties' rights prior to the launch of the biosimilar product. If a notice of commercial marketing could be given at any time before FDA licensure, the RPS would be left to guess the scope of the approved license and when commercial marketing would actually begin. Indeed, filing an aBLA only suggests that a subsection (k) applicant intends to

commercially market its product someday in the future.

Furthermore, requiring FDA licensure before notice of commercial marketing does not necessarily conflict with the twelve-year exclusivity period of § 262(k)(7)(A). It is true that in this case, as we decide *infra*, Amgen will have an additional 180 days of market exclusion after Sandoz's effective notice date; that is because Sandoz only filed its aBLA 23 years after Amgen obtained FDA approval of its Neupogen product. Amgen had more than an "extra" 180 days, but that is apparently the way the law, business, and the science evolved. That extra 180 days will not likely be the usual case, as aBLAs will often be filed during the 12-year exclusivity period for other products. A statute must be interpreted as it is enacted, not especially in light of particular, untypical facts of a given case. Finally, it is counterintuitive to provide that notice of commercial marketing be given at a time before one knows when, or if, the product will be approved, or licensed.

We therefore conclude that, under paragraph (*l*)(8)(A), a subsection (k) applicant may only give effective notice of commercial marketing after the FDA has licensed its product. The district court thus erred in holding that a notice of commercial marketing under paragraph (*l*)(8)(A) may effectively be given before the biological product is licensed, and we therefore reverse its conclusion relating to its interpretation of § 262(*l*)(8)(A) and the date when Sandoz may market its product.

b.

We next consider the consequence in this case of our interpretation of paragraph (*l*)(8)(A). Paragraph (*l*)(8)(A) provides that the subsection (k) applicant "shall provide" notice of commercial marketing to the RPS no later than 180 days before commercial marketing of the licensed product. As we have concluded, an operative notice of commercial marketing can only be given after FDA licensure. Here, Sandoz's notice in July 2014, the day after the FDA accepted its application for review, was premature and ineffective. However, the FDA approved Sandoz's aBLA on March 6, 2015, and Sandoz gave a "further" notice of commercial marketing on that day. J.A. 1774. These facts are uncontested. Oral Argument at 35:33-56, *Amgen Inc. v. Sandoz Inc.*, No. 2015-1499 (Fed. Cir. June 3, 2015), *available at* http://www.cafc.uscourts.gov/oral-argument-recordings/15-1499/all. That notice in March 2015 thus serves as the operative and effective notice of commercial marketing in this case.

A question exists, however, concerning whether the "shall" provision in paragraph (*l*)(8)(A) is mandatory. We conclude that it is. Both paragraph (*l*)(2)(A) and (*l*)(8)(A) use the word "shall," which presumptively signals a statutory requirement. *See, e.g.*, *Nat'l Ass'n of Home Builders v. Defenders of Wildlife*, 551 U.S. 644, 661-62 (2007); *Lopez v. Davis*, 531 U.S. 230, 241 (2001). As we have noted with respect to paragraph (*l*)(2)(A), however, the BPCIA explicitly contemplates that a subsection (k) applicant might fail to comply with the requirement of paragraph (*l*)(2)(A)

and further specifies the consequence for such failure in 42 U.S.C. § 262(*l*)(9)(C) and 35 U.S.C. § 271(e)(2)(C)(ii). Because of those explicit statutory provisions, and to avoid construing the statute so as to render them superfluous, we have interpreted the BPCIA as allowing noncompliance with paragraph (*l*)(2)(A), subject to the consequence specified in those other provisions.

In contrast, with respect to paragraph (*l*)(8)(A), we do not find any provision in the BPCIA that contemplates, or specifies the consequence for, noncompliance with paragraph (*l*)(8)(A) here, which would be the case if Sandoz attempts to launch in disregard of the requirement of paragraph (*l*)(8)(A), as we have interpreted it. Sandoz argues that § 262(*l*)(9)(B) does specify the consequence for noncompliance with paragraph (*l*)(8)(A). Paragraph (*l*)(9)(B), entitled "[s]ubsequent failure to act by subsection (k) applicant," provides that:

> If a subsection (k) applicant *fails to complete* an action required of the subsection (k) applicant under paragraph (3)(B)(ii), paragraph (5), paragraph (6)(C)(i), paragraph (7), or *paragraph (8)(A)*, the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of Title 28, for a declaration of infringement, validity, or enforceability of *any patent included in the list described in paragraph (3)(A), including as provided under paragraph (7).*

42 U.S.C. § 262(*l*)(9)(B) (emphases added).

While it is true that paragraph (*l*)(9)(B) specifies the consequence for a subsequent failure to comply with paragraph (*l*)(8)(A) *after the applicant has complied* with paragraph (*l*)(2)(A), it does not apply in this case, where Sandoz did not comply with paragraph (*l*)(2)(A) to begin with. Indeed, the consequence specified in paragraph (*l*)(9)(B) is a declaratory judgment action brought by the RPS based on "any patent included in the list described in paragraph (3)(A), including as provided under paragraph (7)." 42 U.S.C. § 262(*l*)(9)(B). Here, however, because Sandoz did not provide the required information to Amgen under paragraph (*l*)(2)(A), Amgen was unable to compile a patent list as described in paragraph (*l*)(3)(A) or paragraph (*l*)(7).

Paragraph (*l*)(8)(A) is a standalone notice provision in subsection (*l*), and Sandoz concedes as much. Oral Argument at 39:30-52, *Amgen Inc. v. Sandoz Inc.*, No. 2015-1499 (Fed. Cir. June 3, 2015), *available at* http://www.cafc.uscourts.gov/oral-argument-recordings/15-1499/all. Unlike the actions described in paragraphs (*l*)(3) through (*l*)(7), which all depend on, or are triggered by, the disclosure under paragraph (*l*)(2)(A), nothing in paragraph (*l*)(8)(A) conditions the notice requirement on paragraph (*l*)(2)(A) or other provisions of subsection (*l*). Moreover, nothing in subsection (*l*) excuses the applicant from its obligation to give notice of commercial marketing to the RPS after it has chosen not to comply with paragraph (*l*)(2)(A). The purpose of paragraph (*l*)(8)(A) is clear: requiring notice of commercial marketing be given to

allow the RPS a period of time to assess and act upon its patent rights.

We therefore conclude that, where, as here, a subsection (k) applicant completely fails to provide its aBLA and the required manufacturing information to the RPS by the statutory deadline, the requirement of paragraph (*l*)(8)(A) is mandatory. Sandoz therefore may not market Zarxio before 180 days from March 6, 2015, *i.e.*, September 2, 2015.

III.

We next consider Amgen's unfair competition and conversion claims under California law. After finding that Sandoz did not violate the BPCIA, the district court dismissed Amgen's state law claims with prejudice. We affirm the dismissal based on our interpretation of the BPCIA.[5]

a.

Under Cal. Bus. & Prof. Code § 17200, "unfair competition" includes "any unlawful, unfair or fraudulent business act or practice." Amgen's unfair competition claim is based solely on the "unlawful" prong, which requires a showing that Sandoz acted unlawfully by violating another law, here, according to

[5] In its cross-motion for judgment on the pleadings, Sandoz did not argue preemption as a defense to Amgen's state law claims, and thus the district court did not consider that issue. We therefore do not address preemption in this appeal.

Amgen, the BPCIA. *Davis v. HSBC Bank Nevada, N.A.*, 691 F.3d 1152, 1168 (9th Cir. 2012); *see also Farmers Ins. Exch. v. Superior Court*, 826 P.2d 730, 734 (Cal. 1992). Under California law, UCL remedies are not available when the underlying law expressly provides that the remedies in that law are exclusive. *See* Cal. Bus. & Prof. Code § 17205; *Loeffler v. Target Corp.*, 324 P.3d 50, 76 (Cal. 2014).

As one basis of its unfair competition claim, Amgen alleges that Sandoz violated the BPCIA by failing to comply with § 262(*l*)(2)(A). As we have concluded, Sandoz did not violate the BPCIA by not disclosing its aBLA and the manufacturing information according to § 262(*l*)(2)(A). Sandoz took a path expressly contemplated by 42 U.S.C. § 262(*l*)(9)(C) and 35 U.S.C. § 271(e)(2)(C)(ii), and 35 U.S.C. § 271(e)(4) provides "the only remedies which may be granted by a court" for the alleged violation. We therefore affirm the dismissal of Amgen's unfair competition claim based on the alleged violation of § 262(*l*)(2)(A).

b.

As another basis of its unfair competition claim, Amgen also asserts that Sandoz violated the BPCIA by giving a premature, ineffective, notice of commercial marketing under § 262(*l*)(8)(A) in July 2014, before FDA approval in March 2015. As indicated, under our interpretation of the BPCIA, the July 2014 notice is ineffective, and Sandoz gave the operative notice on March 6, 2015. Thus, as we have indicated, Sandoz may not market Zarxio before 180 days from

March 6, 2015, *i.e.*, September 2, 2015. And, as indicated below, we will extend the injunction pending appeal through September 2, 2015. Amgen's appeal from the dismissal of its unfair competition claim based on the alleged violation of § 262(*l*)(8)(A) is therefore moot.

c.

We now turn to Amgen's conversion claim. To sustain a claim for conversion under California law, Amgen must demonstrate: (1) its ownership or right to possession of the property; (2) Sandoz's conversion by a wrongful act or disposition of property rights; and (3) damages. *Burlesci v. Petersen*, 80 Cal. Rptr. 2d 704, 706 (Cal. Ct. App. 1998). Amgen asserts that Sandoz wrongfully used Amgen's approved license on Neupogen by filing an aBLA referencing Neupogen but refusing to provide Amgen the benefits to which it is entitled under § 262(*l*). Sandoz responds that Amgen failed to show any "wrongful act" or to establish an exclusive ownership interest in the approved license on Neupogen to exclude Sandoz's aBLA.

We agree with Sandoz that Amgen failed to establish the requisite elements to sustain a claim of conversion under California law. As indicated, the BPCIA explicitly contemplates that a subsection (k) applicant might not disclose its aBLA and the manufacturing information by the statutory deadline, and

provides that the RPS may sue for patent infringement, which Amgen has done. Amgen thus failed to show a "wrongful act."

Moreover, the BPCIA established the abbreviated pathway for FDA approval of follow-on biological products, allowing a subsection (k) applicant to use "publicly-available information" regarding the reference product in its application.[6] 42 U.S.C. § 262(k)(2). The BPCIA also grants a 12-year exclusivity period to the RPS, during which approval of a subsection (k) application may not be made effective. *Id.* § 262(k)(7)(A). Neupogen's 12-year exclusivity period has long expired. Amgen therefore fails to show that it has an *exclusive* right to possession of its approved license on Neupogen to sustain its claim of conversion under California law.

We therefore affirm the dismissal of Amgen's unfair competition and conversion claims based on our interpretation of the relevant provisions of the BPCIA.

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[6] Amgen emphasizes in its briefs that Sandoz is wrongfully benefitting from Amgen's establishment of the safety and efficacy of filgrastim. Be that as it may, this is not the first time that Congress has allowed generic applicants to benefit from the early work of innovators. *See* Hatch-Waxman Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984); *see also Ruckelshaus v. Monsanto Co.*, 467 U.S. 986 (1984). That was a decision that Congress was entitled to make and it did so.

IV.

Amgen argues that the district court erred in denying its motion for a preliminary injunction based on an incorrect reading of the BPCIA and an erroneous finding that Amgen failed to show irreparable harm. Sandoz responds that Amgen's appeal is moot because it sought an injunction only until the district court decided the parties' cross-motions for judgment on the pleadings, which has already occurred. Sandoz also responds that, even if not moot, the district court did not abuse its discretion in denying the motion and did not clearly err in its factual findings.

We agree with Sandoz that Amgen's appeal from the denial of a preliminary injunction is moot. In its motion for a preliminary injunction, filed in the district court after it filed its motion for judgment on the pleadings, Amgen requested a preliminary injunction "until the Court decides the parties' motions for judgment on the pleadings," and "if the Court resolves those motions in Amgen's favor, until . . . the parties have been placed in the position they would be in had Sandoz complied with the BPCIA." *Amgen Inc. v. Sandoz Inc.*, No. 14-cv-04741 (N.D. Cal. Feb. 5, 2015), ECF No. 56, at 25.

On March 19, 2015, the district court rendered its decision on the parties' cross-motions for judgment on the pleadings, deciding against Amgen on the merits and dismissing Amgen's state law claims with prejudice. In the same order, the court also denied Amgen's motion for a preliminary injunction, which

was based solely on its state law claims. Because Amgen only requested a preliminary injunction until the district court decided the parties' motions for judgment on the pleadings, and the district court has resolved those motions against Amgen, Amgen's appeal from the denial of a preliminary injunction is moot. We therefore dismiss that aspect of Amgen's appeal.

V.

After the district court granted partial judgment on the pleadings in favor of Sandoz and denied Amgen's motion for a preliminary injunction, Amgen sought an injunction pending appeal, which the district court denied. Amgen then filed an emergency motion in this court for an injunction pending appeal. We granted the motion. In light of what we have decided concerning the proper interpretation of the contested provisions of the BPCIA, we accordingly order that the injunction pending appeal be extended through September 2, 2015.

C. Conclusion

For the foregoing reasons, we affirm the dismissal of Amgen's unfair competition and conversion claims, vacate the district court's judgment on Sandoz's counterclaims interpreting the BPCIA, and direct the district court to enter judgment on those counterclaims consistent with this opinion. We also remand for the district court to consider the patent

infringement claim and counterclaims relating to the '427 patent and any other patents properly brought into the district court action.

AFFIRMED IN PART, VACATED IN PART, AND REMANDED

COSTS

Each party shall bear its own costs.

NEWMAN, *Circuit Judge*, concurring in part, dissenting in part.

The immediate issue relates to the Biosimilar Price Competition and Innovation Act (BPCIA) and certain obligations of the innovator/patentee (called the "reference product sponsor," or "Sponsor") and the subsection (k) applicant. Subsection (k) authorizes a biosimilar applicant to use the Sponsor's clinical safety and efficacy data in order to obtain FDA license approval for commercial marketing of the biosimilar product. By acting under subsection (k) the applicant need not obtain its own clinical data for its biosimilar product, and can receive FDA licensure by showing that "the biological product is biosimilar to a reference product," 42 U.S.C. §262(k), and has the same characteristics of safety, efficacy, and purity. *Id.*

To facilitate identification of and resolution of any patent issues, the BPCIA requires the subsection (k) applicant to notify the Sponsor at two critical stages of FDA review of the subsection (k) application.

I agree with the court that notice of issuance of the FDA license is mandatory, and that this notice starts the 180-day stay of commercial marketing, in accordance with 42 U.S.C. §262(*l*)(8)(A). Thus I join Part A, Part (B)(II), and Part B(V) of the court's opinion.

However, notice of acceptance of the filing of the subsection (k) application is also mandatory, along with the accompanying documentary and information exchanges set in the BPCIA in accordance with 42 U.S.C. §262(*l*)(2)(A). I respectfully dissent from the court's holding that this activity is not required because the Sponsor might file an infringement suit in which it might learn this information though discovery.

Sandoz did not comply with either of these statutory requirements. These deliberate violations of the requirements of the BPCIA forfeit Sandoz' access to the benefits of the BPCIA.

I

Patent dispute resolution under the BPCIA has two phases. The "early phase" starts when the subsection (k) application is accepted by the FDA for review, and technical and patent information are then exchanged. The "later phase" starts when the FDA approves the biosimilar for commercial marketing. I comment only briefly on this later phase, for I agree, as the court holds, that 42 U.S.C. §262(*l*)(8) requires that this phase of inquiry and dispute resolution commences when the subsection (k) applicant notifies

the Sponsor, after the FDA license is granted. My concern is that my colleagues on this panel do not apply, to the earlier "shall provide" words, the same mandatory meaning as for subsection (*l*)(8)(A):

> §**262(*l*)(8)(A)** *Notice of commercial marketing.*—The subsection (k) applicant **shall provide notice** to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product **licensed under subsection (k).**

(Emphases added). The BPCIA explicitly states that after licensure and before commercial marketing the Sponsor may seek a preliminary injunction while the patent aspects are resolved:

> §**262(*l*)(8)(B)** *Preliminary injunction.*—After receiving the notice under subparagraph (A) and before such date of the first commercial marketing of such biological product, the reference product sponsor **may seek a preliminary injunction** prohibiting the subsection (k) applicant from engaging in the commercial manufacture or sale of such biological product until the court decides the issue of patent validity, enforcement, and infringement [of any patent identified in the early stage or other defined proceedings.]

(Emphasis added). Sandoz proposed to circumvent this provision and launch its biosimilar product immediately upon its FDA licensure.

I share the court's interpretation of this statutory provision, which implements the purpose of the BPCIA "to ensure that litigation surrounding relevant patents will be resolved expeditiously and *prior to the launch* of the biosimilar product, providing certainty to the applicant, the reference product manufacturer, and the public at large." *Biologics and Biosimilars: Balancing Incentives for Innovation: Hearing Before the Subcommittee On Courts and Competition Policy of the House Committee On the Judiciary*, 111th Cong. 9 (July 14, 2009) (statement of Rep. Eshoo) (emphasis added). The BPCIA requires the court to give effect to the intent of Congress. *See Ingersoll-Rand Co. v. McClendon*, 498 U.S. 133, 138 (1990) ("To discern Congress' intent we examine the explicit statutory language and the structure and purpose of the statute.")

II

The BPCIA provides for participants' recognition of potential patent issues at an early stage, and requires that as soon as the FDA accepts the biosimilar application for review, the subsection (k) applicant *shall* notify the Sponsor, and exchanges of patent-related information *shall* commence. Details are set forth in 42 U.S.C. §262(*l*)(2). My colleagues hold that compliance with these early notice and information provisions is not mandatory. I cannot agree, for: "The word 'shall' is ordinarily the language of command." *Alabama v. Bozeman*, 533 U.S. 146, 153 (2001).

The purpose of subsection 262(*l*) is to initiate patent-related activity, to exchange relevant information, to facilitate negotiations, and to expedite any litigation. Subsection (*l*)(2)(A) requires the subsection (k) applicant to notify the Sponsor within 20 days after the FDA accepts the subsection (k) application for review, and to describe the manufacturing process:

> §**262(*l*)(2)(A)** *Subsection (k) application information.*—Not later than 20 days after the Secretary notifies the subsection (k) applicant that the application has been accepted for review, the subsection (k) applicant **shall provide** to the reference product sponsor a copy of the application submitted to the Secretary under subsection (k), and such other information that describes **the process or processes used to manufacture** the biological product that is the subject of such application.

(Emphases added). Sandoz did not provide this information, although it is required, and the BPCIA provides for confidentiality:

> §**262(*l*)(1)(B)(i)** *Provision of confidential information.*—When a subsection (k) applicant submits an application under subsection (k), such applicant **shall provide** to the persons described in clause (ii), subject to the terms of this paragraph, **confidential access to the information required** to be produced pursuant to paragraph (2) and any other information that the subsection (k) applicant

> determines in its sole discretion to be appropriate.

(Emphases added).

This designated exchange of information is fundamental to the BPCIA purposes of efficient resolution of patent issues. However, my colleagues hold that compliance by the applicant is not mandatory, citing §262(*l*)(9)(C), which authorizes suit by the Sponsor if the applicant does not provide the paragraph (2)(A) information:

> **§262(*l*)(9)(C)** *Subsection (k) application not provided.*—If a **subsection (k) applicant fails to provide** the application and information required under paragraph (2)(A), the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of Title 28, for a declaration of infringement, validity, or enforceability of any patent that claims **the biological product or a use** of the biological product.

(Emphases added). This provision for declaratory action by the Sponsor is limited to "product" and "use" claims, and does not include manufacturing process patents, although the legislative record makes clear that for biosimilars such patents may be highly material, and were so recognized during enactment. Amgen states that its patents here at issue relate primarily to manufacture.

I cannot agree that this provision excuses compliance by the subsection (k) applicant, even when

such declaratory action is brought. Subsection (*l*)(9)(C) provides declaratory jurisdiction only for product or use claims. Absent adequate factual support in a complaint for manufacturing method claims, declaratory jurisdiction may be unsupported. *See Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) ("To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to "state a claim to relief that is plausible on its face.") (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)).

The balance established in the BPCIA requires the statutorily identified disclosures at the threshold, in order both to avert and to expedite litigation. This purpose pervades the legislative record, as interested persons debated which provisions would be mandatory, and which permissive. *See, e.g., Biologics and Biosimilars: Balancing Incentives for Innovation: Hearing Before the Subcommittee on Courts and Competition Policy of the House Committee on the Judiciary*, 111th Cong. *passim* (2009) (debating the provisions of H.R. 1548, which provided for mandatory patent exchange, and H.R. 1427, which provided for discretionary patent exchange). *Compare also* S. 623, 110th Cong. § (3)(a)(2)(k)(17)(E) (2007) ("nothing in this paragraph requires an applicant or prospective applicant to invoke the [patent notification and exchange] procedures set forth in this paragraph") *with* S. 1695, 110th Cong. § (2)(a)(2)(*l*)(2)(A) (2007) (the subsection (k) applicant "shall provide" application and manufacturing information). *See Chickasaw Nation v. United States*, 534 U.S. 84, 93 (2001) ("We

ordinarily will not assume that Congress intended 'to enact language that it has earlier discarded in favor of other language.'" (citations omitted)).

The BPCIA as enacted leaves no uncertainty as to which of its provisions are mandatory and which are permissive. For example, immediately after the **"shall"** provision of subsection *(l)*(2)(A), *ante*, subsection (*l*)(2)(B) states that a subsection (k) applicant

> **may** provide to the reference product sponsor **additional** information requested by or on behalf of the reference product sponsor.

(Emphases added). "[W]hen the same Rule uses both 'may' and 'shall', the normal inference is that each is used in its usual sense—the one act being permissive, the other mandatory." *Anderson v. Yungkau*, 329 U.S. 482, 485 (1947).

In *United States ex rel. Siegel v. Thoman*, 156 U.S. 353, 359-60 (1895), the Court stated that when Congress uses the "special contradistinction" of "shall" and "may," no "liberty can be taken with the plain words of the statute." As reiterated in *Sebelius v. Cloer*, 133 S. Ct. 1886, 1894 (2013), "[w]here Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion." (alteration and internal quotation marks omitted). The BPCIA gestated during more than four years of study and debate. The record contains frequent reference to the experience of the

Hatch-Waxman Act, as the BPCIA departed from that Act in seeking to "balance innovation and consumer interests" in the new and promising scientific era of biosimilars. BPCIA, Pub. L. No. 111-148, §7001(b), 124 Stat. 119, 804 (2010). Fidelity to that balance is the judicial obligation.

The details enacted and included in the BPCIA demonstrate the rigor of the statute and its compromises. The BPCIA requires judicial implementation that conforms to "the design of the statute as a whole and to its object and policy." *Crandon v. United States*, 494 U.S. 152, 158 (1990). Subsection (k) and subsection (*l*) are components of an integrated framework; to enjoy the benefits of subsection (k), the biosimilar applicant is obligated to comply with subsection (*l*). Even on the district court's (and my colleagues') misplaced theory that subsection (*l*)(9)(C) excuses compliance with subsection (*l*)(2)(A), this would extend only to product and use claims, it does not excuse compliance as to manufacturing and process claims.

The BPCIA reflects an explicit balance of obligations and benefits. When a beneficiary of the statute withholds compliance with provisions enacted to benefit others, the withholder violates that balance. The consequences of the majority's ruling are significant, for the structure of the BPCIA requires that the subsection (k) applicant comply with the information

exchange provisions, as a threshold to resolution of the Sponsor's patent rights.[1]

Subsection (*l*)(9) provides jurisdiction in the district court when a subsection (k) applicant fails to comply with subsection (*l*), but it does not ratify non-compliance. While "a party may waive any provision, either of a contract or of a statute, intended for his benefit," *United States v. Mezzanatto*, 513 U.S. 196, 201 (1995), the party cannot waive or disregard a provision that benefits those in an adverse position. The provisions of 35 U.S.C. §262(*l*)(9) function as a continuing prohibition on a party who fails to comply with some aspect of the patent exchange provisions. That is, subsection (*l*)(9)(C) prevents a non-compliant party from obtaining relief through a declaratory judgment action, while that prohibition is lifted as to the aggrieved party. Subsection (*l*)(9)(C) states that a "reference product sponsor, but not the subsection (k) applicant, may bring" a declaratory judgment action "for a declaration of infringement, validity, or enforceability for any patent that claims the biological

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[1] The record recites the benefits of subsection (k) for biosimilar applicants. A study for the Congressional Research Service cites a Tufts report that found in 2006 the "average cost to develop a new biotechnology product is $1.2 billion." *Follow-On Biologics: The Law and Intellectual Property Issues, CRS Report for Congress*, Professor John Thomas, January 15, 1014, *passim*, n.32. The record explains that clinical safety and efficacy studies constitute the major portion of this development cost, and that subsection (k) authorizes the biosimilar applicant to rely on these data that the Sponsor provided to the FDA.

product or use of the biological product" when a subsection (k) applicant fails to provide the information required under subsection (*l*)(2)(A).

35 U.S.C. § 271(e)(2)(C)(ii) similarly states that it shall be an act of infringement if the applicant fails to provide the information required under paragraph (*l*)(2)(A). However, this does not diminish the obligation set by section (*l*)(1)(B)(i) that the subsection (k) applicant "shall provide . . . confidential access to the information required to be produced pursuant to paragraph (2)." Such obligation is mandatory.

Departure from the statutory obligation, to achieve purposes that the legislation intended to curtail, should not be judicially ratified. *See Cannon v. Univ. of Chicago*, 441 U.S. 677, 690 (1979) (disregard of a statute is a wrongful act). It is not denied that Sandoz obtained the benefit of the Amgen data in filing under subsection (k). Sandoz should be required to respect its obligations, in fidelity to the statute. I respectfully dissent from the majority's failure to require compliance with the obligations of the BPCIA.

CHEN, *Circuit Judge*, dissenting-in-part.

I join the majority opinion except for Parts B.II.b and B.V. To properly interpret the BPCIA's patent litigation management process described in section 262(*l*), I agree that none of subsection (*l*)'s provisions may be read in isolation. In other words, to understand

the meaning of any one provision in § 262(*l*), one must first recognize how it interrelates with the rest of subsection (*l*) and the rest of the BPCIA. Based on this understanding, I agree that a subsection (k) applicant's failure to supply the information described in (*l*)(2) to the reference product sponsor (RPS) is not a violation of the BPCIA, because the BPCIA itself, in (*l*)(9) and § 271(e)(2)(C)(ii), provides the RPS the remedial course of action in such circumstances. Contrary to the majority, however, I view this context-based interpretation as applying with equal force to the interpretation of (*l*)(8). When reading (*l*)(8) in the context of subsection (*l*) as a whole, it becomes clear that (*l*)(8) is simply part and parcel of the integrated litigation management process contemplated in (*l*)(2)-(*l*)(7). Moreover, just as all the "shall" obligations set forth in (*l*)(3)-(*l*)(7) are contingent on the (k) applicant's performance of the first "shall" step in (*l*)(2), this is also true of the "shall" notice obligation in (*l*)(8). What this means is when, as here, the (k) applicant fails to comply with (*l*)(2), the provisions in (*l*)(3)-(*l*)(8) cease to matter. In such a situation, as recognized by the majority opinion, the RPS's course of action is clearly defined in (*l*)(9) and § 271(e)(2)(C)(ii): the unfettered right to immediately pursue patent infringement litigation unconstrained by any of the timing controls or limits on the number of patents it may assert that would result from the (*l*)(2)-(*l*)(8) process. Based on this understanding, I do not view (*l*)(8)(A) as a "standalone provision" that provides, implicitly, the RPS a 180-day injunction beyond the express twelve-year statutory exclusivity

period. Because the majority opinion interprets (*l*)(8) differently, giving Amgen, the RPS, an extra-statutory exclusivity windfall, I respectfully dissent.

I

"It is a fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme." *Davis v. Mich. Dep't of Treasury*, 489 U.S. 803, 809 (1989). To that end, the Supreme Court has instructed that "statutory language cannot be construed in a vacuum." *Id.*; *see also Yates v. United States*, 135 S. Ct. 1074, 1081-82 (2015) (instructing courts to interpret statutory text by reference to "the specific context in which that language is used, and the broader context of the statute as a whole." (quotation marks omitted)). In Part B.I, the majority properly recognizes that "the 'shall' provision in paragraph (*l*)(2)(A) cannot be read in isolation." Majority Op. at 12 [*supra* p. 15a]. The majority carefully examines the larger statutory context—subsection (*l*) and § 271(e)(2)(C)(ii)—and correctly concludes that "'shall' in paragraph (*l*)(2)(A) does not mean 'must.'" Majority Op. at 13 [*supra* p. 15a]. As the majority recognizes, nothing in the BPCIA grants the RPS a procedural right to *compel* the (k) applicant's compliance with (*l*)(2)(A). In Part B.II, however, the majority holds that the word "shall" in (*l*)(8)(A) carries a different meaning than it does in (*l*)(2)(A). To reach that inconsistent result, the majority takes the view that (*l*)(8)(A) should be read in a vacuum, apart

from the context and framework of subsection (*l*), including the language of (*l*)(8)(B). I respectfully disagree.

A

Entitled "Patents," § 262(*l*) of the BPCIA concerns one thing: patent litigation. Specifically, it specifies an elaborate information exchange process between the (k) applicant and the RPS that leads up to the expected patent infringement suit that comes during the pendency of a subsection (k) application. This process begins in (*l*)(2)(A) with the requirement that the (k) applicant disclose to the RPS its biosimilar application (aBLA) and manufacturing process information. Compliance with subsection (*l*)(2)(A) triggers a cascade of events contemplated by subsection (*l*), with each successive step reliant on the performance of one or more preceding steps. This intricate process includes: the exchange of patent lists that each party believes the RPS has reasonable grounds to assert against the (k) applicant, as well as the exchange of respective infringement, validity, and enforceability positions (§ 262(*l*)(3)); a process by which the parties may limit the patents in the infringement lawsuit (§ 262(*l*)(4)-(5)); a patent infringement lawsuit, filed by the RPS, limited to the patents listed in (*l*)(4) or (*l*)(5) (§ 262(*l*)(6)); a procedure for updating the RPS's previously created (*l*)(3) patent list with newly issued or licensed patents (§ 262(*l*)(7)); a requirement that the (k) applicant provide a 180-day notice ahead of commercial marketing thereby giving the RPS time to seek a preliminary

injunction on any (*l*)(3) listed patents not asserted in the limited (*l*)(6) patent infringement suit (§ 262(*l*)(8)); and authorization for the RPS to file an immediate declaratory judgment action for patent infringement if the (k) applicant fails to comply with its specified obligations recited in (*l*)(2), (*l*)(3), (*l*)(5), (*l*)(6), (*l*)(7), or (*l*)(8) (§ 262(*l*)(9)(B)-(C)). Importantly, subsection (*l*) does not relate to the FDA approval process (for that see subsection (k)). Nor is the approval process contingent on any events related to a possible patent dispute occurring in parallel with that approval process.

By enacting the provisions in subsection (*l*), Congress created a comprehensive, integrated litigation management system. These provisions also demonstrate that Congress anticipated the situation before us here, in which the (k) applicant refuses to engage in this litigation management process. Rather than forcing the (k) applicant, by court order or some other means, to engage in the subsection (*l*) process, or conditioning the (k) application's approval on the (k) applicant fulfilling the requirements set forth in subsection (*l*), Congress instead authorized the RPS in this situation to immediately file an infringement action. *See* § 262(*l*)(9) and 35 U.S.C. § 271(e)(2)(C)(ii).

Focusing on (*l*)(8), Congress accounted for the possibility (perhaps strong likelihood) of a situation in which the (k) applicant has received FDA approval and is on the verge of commercially marketing its biosimilar product but the RPS was unable to assert all of its (*l*)(3) listed patents against the (k) applicant

in the limited (*l*)(6) patent litigation. Entitled "Notice of commercial marketing and preliminary injunction," (*l*)(8), in relevant part, is set forth below:

> **8) Notice of commercial marketing and preliminary injunction**
>
> **(A)** Notice of commercial marketing
>
> The subsection (k) applicant shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k).
>
> **(B)** Preliminary injunction
>
> After receiving the notice under subparagraph (A) and before such date of the first commercial marketing of such biological product, the reference product sponsor may seek a preliminary injunction prohibiting the subsection (k) applicant from engaging in the commercial manufacture or sale of such biological product until the court decides the issue of patent validity, enforcement, and infringement with respect to any patent that is—
>
> > **(i)** included in the list provided by the reference product sponsor under paragraph (3)(A) or in the list provided by the subsection (k) applicant under paragraph (3)(B); and
> >
> > **(ii)** not included, as applicable, on—

> **(I)** the list of patents described in paragraph (4); or
>
> **(II)** the lists of patents described in paragraph (5)(B).

Subsection (*l*)(8)(A) requires the (k) applicant to give the RPS at least 180 days' notice of its intent to begin commercially marketing the biosimilar product. One of the key questions in this appeal is, "Why would Congress insert a 180-day commercial marketing notice provision in a subsection devoted to organizing patent litigation?" Paragraph (*l*)(8)(B) provides the answer. As mentioned above, the process in (*l*)(4)-(5) can result in restricting the (*l*)(6) infringement action to a subset of the RPS's patents identified in (*l*)(3). Rather than permit the (k) applicant to launch its biosimilar product while the RPS is blocked from enforcing some of its patent rights, subsection (*l*)(8)(B) addresses that problem by authorizing the RPS to seek a preliminary injunction prohibiting commercial manufacture or sale based on the patents that were excluded from the (*l*)(6) action. Thus, the entirety of (*l*)(8), including (*l*)(8)(A)'s notice provision, serves to ensure that an RPS will be able to assert all relevant patents before the (k) applicant launches its biosimilar product. Amgen confirmed this understanding of (*l*)(8)'s purpose at oral argument. Oral Argument at 20:10-20:05, *Amgen, Inc. v. Sandoz Inc.*, No. 2015-1499 (Fed. Cir. June 3, 2015), *available at* http://www.cafc.uscourts.gov/oral-argument-recordings/15-1499/all.

Given the purpose of (*l*)(8) and its express assumption that the parties have already performed the steps in (*l*)(3), and (*l*)(4)-(*l*)(5), the most logical conclusion when reading (*l*)(8) in context is that (*l*)(8)'s vitality is predicated on the performance of the preceding steps in subsection (*l*)'s litigation management process. Without first engaging in these procedures, (*l*)(8) lacks meaning. Similarly, for example, the statutory requirement in (*l*)(3) for the parties to exchange detailed positions on infringement and validity for the patents listed under (*l*)(3) no longer applies if the (k) applicant fails to comply with (*l*)(2). Paragraph (*l*)(8)'s interdependency on the preceding steps in subsection (*l*) is further reinforced by (*l*)(7)'s cross-reference to (*l*)(8). Paragraph (*l*)(7), which sets forth a process for the RPS to update its (*l*)(3) patent list with any newly issued or licensed patents, states that any such patents "shall be subject to paragraph (8)." 42 U.S.C. § 262(*l*)(7)(B). The interwoven structure of subsection (*l*) indicates that Congress viewed the procedures of (*l*)(8) as inseverable from the preceding steps in (*l*).

The majority, on the other hand, views (*l*)(8)(A) as a standalone notice provision that is not excused when the (k) applicant fails to comply with (*l*)(2).[1] Yet,

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[1] The majority states that Sandoz "concedes" that (*l*)(8)(A) is a standalone notice provision, citing to the oral argument. I understand Sandoz's position as accepting that (*l*)(8)(A) as a standalone provision is one possible interpretation. Oral Argument at 39:30-40:30, *Amgen Inc. v. Sandoz Inc.*, No. 2015-1499

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no one disputes that the requirements of (*l*)(3) through (*l*)(7) are certainly excused in such a case. I recognize that (*l*)(8)(A), unlike (*l*)(3) through (*l*)(7), is not expressly conditioned on the earlier steps. I cannot, however, read (*l*)(8)(A) in complete isolation from (*l*)(8)(B), which *does* reference, and is predicated on the performance of, (*l*)(3) and (*l*)(4)-(*l*)(5). Thus, (*l*)(8) does not serve as a standalone provision; it is part and parcel to, and contingent upon, the preceding steps in the (*l*)(2)-(*l*)(8) litigation management regime. The most persuasive reading of subsection (*l*) as a whole is that Congress provided two paths to resolve patent disputes: (1) the intricate route expressed in (*l*)(2)-(*l*)(8); and (2) the immediate, more flexible route provided in (*l*)(9), should the (k) applicant falter on any of its obligations recited in (*l*)(2)-(*l*)(8).

B

The majority is also concerned with the absence of an express consequence for noncompliance with (*l*)(8)(A) in situations in which the (k) applicant does not comply with (*l*)(2). I agree with the majority that the remedy in (*l*)(9)(B) does not provide relief in this scenario because the RPS's right to pursue additional patent litigation at this stage under (*l*)(9)(B) is contingent on using the patents that have been "included

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(Fed. Cir. June 3, 2015), *available at* http://www.cafc.uscourts.gov/oral-argument-recordings/15-1499/all.

in the list described in paragraph (3)(A)." If a (k) applicant never carries out (*l*)(2), the RPS will never create an (*l*)(3) patent list. Such a failure to adhere to (*l*)(2) would defeat the RPS's opportunity to invoke (*l*)(9)(B) if the (k) applicant refuses to comply with (*l*)(8)(A)'s notice provision.

Contrary to the majority's conclusion, however, the absence of such a remedial provision in (*l*)(9)(B) *confirms* that Congress deemed any additional remedy to be unnecessary. Congress created the fallback provision of (*l*)(9)(C) for just these circumstances. An RPS does not need the remedy in (*l*)(9)(B) because (*l*)(9)(C) and § 271(e)(2)(C)(ii) already grant the right to file, immediately, an unrestricted patent infringement action when the (k) applicant fails to comply with (*l*)(2). At this point, the RPS possesses the statutory right to seek a preliminary injunction for any of its patents that "could be identified pursuant to section [262](*l*)(3)(A)(i)." 35 U.S.C. § 271(e)(2)(C)(ii). It therefore would have been superfluous for Congress to provide the RPS with authorization to initiate an additional, redundant infringement action under (*l*)(9)(B)[2] if the (k) applicant later does not

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[2] It is worth examining (*l*)(9)(B) closely for it shows how Congress understood the (*l*)(8) notice provision to be one part of the entire subsection (*l*) litigation management process. Under (*l*)(9)(B), if a (k) applicant fails to comply with any of its obligations recited in "paragraph (3)(B)(ii), paragraph (5), paragraph (6)(C)(i), paragraph (7), *or paragraph (8)(A)*," the RPS may immediately bring an infringement action on any patent the RPS listed in (*l*)(3). 42 U.S.C. § 262(*l*)(9)(B) (emphasis added).

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comply with (*l*)(8)(A). Not only is compliance with (*l*)(8)(A) unnecessary under such a circumstance, but no additional remedy is needed. Thus, after Sandoz failed to perform the (*l*)(2) requirement, the only relevant provision in subsection (*l*) became (*l*)(9)(C) and § 271(e)(2)(C)(ii).

C

The practical consequence of the majority's interpretation is that (*l*)(8)(A) provides an inherent right to an automatic 180-day injunction. The majority provides no basis in the statutory language to support this automatic injunction.[3] This relief is analogous to the thirty-month stay of the Hatch-Waxman Act, which provides for an automatic stay during which the FDA cannot approve the ANDA unless the patent infringement suit is resolved or the patent expires. *See* 21 U.S.C. § 355(j)(5)(B)(iii). If

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By grouping (*l*)(8)(A) with (*l*)(3), (*l*)(5), (*l*)(6), and (*l*)(7), all of which are unquestionably part of the litigation management regime, and defining the scope of any infringement action by the patents listed in (*l*)(3), Congress evidenced that (*l*)(8)(A) is *not* a provision that stands apart from the others, but is instead part of an integrated regime with each part serving a common purpose.

[3] The majority believes that (*l*)(8)(A)'s notice provision plays a necessary role, when the (k) applicant fails to comply with (*l*)(2), to provide the RPS adequate notice of the aBLA and therefore a meaningful opportunity to assert its patent rights. In my view, the majority reads too much into (*l*)(8)(A) by empowering it with an injunction right in the limited circumstance when a (k) applicant fails to comply with (*l*)(2).

Congress intended to create a 180-day automatic stay it understood how to do so. It could have tied FDA approval to the notice provision. Yet, Congress declined to link FDA approval to a single provision in subsection (*l*). At bottom, the majority's view is in tension with the defined purpose of (*l*)(8) while providing the RPS with an atextual 180-day exclusivity windfall.

Notably, nothing in the majority opinion suggests that this automatic injunction remedy would be available in cases where the applicant complied with (*l*)(2)(A) by providing its aBLA to the RPS, but later failed to provide notice under (*l*)(8)(A). In fact, the majority's opinion creates an uncomfortable result in which the language of (*l*)(8)(A) is interpreted in two different ways, based on the (k) applicant's actions. In a situation like the present case, the (k) applicant cannot refuse to provide the 180-days' notice, because under the majority's reading, (*l*)(8)(A) authorizes an automatic entitlement to a 180 day injunction. But if a (k) applicant complies with all the requirements specified in (*l*)(2)-(*l*)(7), then the (k) applicant may still refuse to comply with the 180-day notice provision. In this scenario, there would be no automatic injunction because (*l*)(9)(B) provides the RPS with the authorization to immediately file suit on any patent it listed under (*l*)(3). Thus, in one scenario, (*l*)(8)(A) provides a 180-day injunction, but in the second scenario it does not. While the result in the latter scenario comes from the plain language of the statute, not so with the former. Nothing in the statute

supports this peculiar outcome. As explained above, in my view, the better reading of (*l*)(8) is that it does not apply, just as (*l*)(3)-(*l*)(7) do not apply, when the (k) applicant fails to comply with (*l*)(2).

II

To be sure, (*l*)(8)(A) is an integral part of the procedures for managing patent litigation that arises as a result of a party filing an aBLA. Nevertheless, (*l*)(8)(A) is simply one piece of subsection (*l*)'s integrated patent dispute puzzle that ceases to matter, just like all the other pieces preceding (*l*)(8) cease to matter, once the (k) applicant fails to comply with (*l*)(2). I do not find support in the statutory language to create an automatic 180-day injunction. Just as "shall" in (*l*)(2) does not mean "must," the same is true for the "shall" provision in (*l*)(8)(A), once it is read in context with the entirety of subsection (*l*).

As the majority opinion recognizes, this case requires us to "unravel the riddle, solve the mystery, and comprehend the enigma" that is the BPCIA. Majority Op. at 3 [*supra* p. 4a] n.1. To fulfill our judicial obligation "to say what the law is," we must choose from a series of imperfect choices. In my view, the most coherent interpretation of (*l*)(8)(A) that is consistent with the rest of the BPCIA is the one I have described above. For these reasons, I respectfully dissent from the majority's holding that (*l*)(8) is a standalone provision with an inherent right to a

180-day injunction. Accordingly, I would dissolve the injunction pending appeal.

APPENDIX B

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

AMGEN INC., et al.,

Plaintiffs,

v.

SANDOZ INC., et al.,

Defendants.

Case No. 14-cv-04741-RS

ORDER ON CROSS MOTIONS FOR JUDGMENT ON THE PLEADINGS AND DENYING MOTION FOR PRELIMINARY INJUNCTION

(Filed Mar. 19, 2015)

I. INTRODUCTION

This dispute arises from conflicting interpretations of the Biologics Price Competition and Innovation Act ("BPCIA"), which established an abbreviated pathway for producers of biologic products deemed sufficiently similar to products already on the market ("biosimilars") to receive Food and Drug Administration ("FDA") license approval. *See* 42 U.S.C. § 262(k), (*l*). The BPCIA allows a drug maker who demonstrates the biosimilarity of its product to one which has already received FDA approval (the "reference product") to rely on studies and data completed by the reference product producer ("reference product sponsor"), saving years of research and millions in costs. Through its amendments to both 42 U.S.C. § 262 and 35 U.S.C. § 271, the BPCIA also enabled a process for resolving patent disputes arising from biosimilars,

whereby applicants and sponsors may participate in a series of disclosures and negotiations aimed at narrowing or eliminating the prospect of patent litigation. While engagement in the process creates a temporary safe harbor from declaratory judgment actions, a party's failure to participate permits the opposing party to commence patent litigation.

Plaintiffs Amgen, Inc. and Amgen Manufacturing, Ltd. (collectively "Amgen") have produced and marketed the biologic product filgrastim under the brand-name Neupogen since 1991. They aver that defendants Sandoz, Inc., Sandoz International GMBH, and Sandoz GMBH,[1] who in July 2014 applied to the FDA to receive biosimilar status for their filgrastim product in order to begin selling it in the United States, behaved unlawfully under 42 U.S.C. § 262 by failing to comply with its disclosure and negotiation procedures. Amgen alleges these transgressions give rise to claims under California's Unfair Competition Law ("UCL") and for conversion, as well as patent infringement as to U.S. Patent No. 6,162,427 ("'427 patent"). Sandoz counterclaims for declaratory judgment adopting its interpretation of the BPCIA and finding its conduct permissible as to Amgen's UCL and conversion claims; and for noninfringement and invalidity of the '427 patent. The parties each filed

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[1] Of the named defendants, only Sandoz, Inc. has responded to Amgen's suit thus far. Sandoz, Inc. will be referred to herein simply as "Sandoz."

cross-motions for partial judgment on the pleadings.[2] Amgen, in addition, requests a preliminary injunction to forestall Sandoz's market entry until a disposition on the merits has issued.[3]

While there is no dispute that Sandoz did not engage in 42 U.S.C. § 262's disclosure and dispute resolution process, its decision not to do so was within its rights. Amgen's motion for partial judgment on the pleadings or partial summary judgment in the alternative is, accordingly, denied, and its UCL and conversion claims are dismissed with prejudice. As the BPCIA does not bar Sandoz's counterclaims for non-infringement and invalidity of the '427 patent, these claims may advance. In addition, Amgen's motion for preliminary injunction is, accordingly, denied.

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[2] Amgen notes that, while the standards under these rules are similar, it brings its motion under both Rule 12(c) and Rule 56 to account for conflicting case law as to whether a court may rule only as to certain claims, but not others, on a motion for judgment on the pleadings.

[3] Since then, however, the parties stipulated that Sandoz would not market its product until the earlier of either a partial judgment on the pleadings in its favor, or April 10, 2015. Sandoz further agreed that, should it receive a favorable ruling before April 10, 2015, it will give Amgen five days' notice before launching its product.

II. BACKGROUND

A. Relevant Provisions of the BPCIA

The dispute presented in the pending motions exclusively concerns questions of law—specifically, of statutory interpretation, as to several provisions in 42 U.S.C. § 262 and 35 U.S.C. § 271(e), both amended in 2010 via Congress's enactment of the BPCIA. The Act's stated purpose was to establish a "biosimilars pathway balancing innovation and consumer interests." Biologics Price Competition and Innovation Act, § 7001(b), Pub. L. No. 111-148, 124 Stat 804 (2010). At issue in particular are two central provisions of 42 U.S.C. § 262: (1) paragraphs (*l*)(2)-(*l*)(6), which lay forth the disclosure and negotiation process that commences with an applicant sharing its Biologic License Application ("BLA") and manufacturing information with the reference product sponsor within twenty days of receiving notice that the FDA has accepted the application for review; and (2) paragraph (*l*)(8), requiring an applicant to give the sponsor at least 180 days' advance notice of the first commercial marketing of its biosimilar. Understanding these particular provisions requires a review of the statutory context.

Subsection (a) of 42 U.S.C. § 262 sets forth standards for FDA approval of biologic products. Among other requirements, applicants must demonstrate that their products are safe, pure, and potent. Subsection 262(k) establishes an abbreviated pathway by which a product "biosimilar" to one previously

approved under subsection (a) (a "reference product") may rely on the FDA's prior findings of safety, purity, and potency to receive approval. According to subsection (k), any entity which demonstrates its biologic product is sufficiently similar to a reference product may apply for an FDA license to market its biosimilar product. Applications must include publicly available information as to the FDA's prior determination of the reference product's safety, purity, and potency, and may include additional publicly available information. 42 U.S.C. § 262(k)(2)(A).

The FDA may not approve a biosimilarity application until twelve years after the date on which the reference product was first licensed under subsection (a); in other words, reference products are entitled to twelve years of market exclusivity. Biosimilarity applicants are precluded from even submitting applications under subsection (k) until four years after the licensing of the reference product. 42 U.S.C. § 262(k)(7)(A), (B).

Subsection 262(*l*) sets forth a process and timeline by which an applicant and reference product sponsor "shall" participate in a series of informational exchanges regarding potential disputes over patent validity and infringement. As long as both parties continue to comply with these disclosure and negotiation steps, neither may bring a declaratory action regarding patent validity, enforceability, or infringement against the other until the applicant provides notice of its upcoming first commercial marketing. 42 U.S.C. § 262(*l*)(9)(A)-(C).

The BPCIA also added to 35 U.S.C. § 271, which governs patent infringement, a provision rendering it "an act of infringement to submit" a subsection (k) application based on a patent the reference product sponsor identified (or could have identified) as infringed by the applicant's biosimilar product under subsection (*l*)'s disclosure and negotiation procedures. 35 U.S.C. § 271(e)(2)(C). In addition to enabling a reference product sponsor to initiate an infringement action for an applicant's reliance on its product, subsection 271(e) sets forth remedies for instances in which liability for infringement is found. Where the sponsor identified or could have identified the infringed patent on its initial disclosure to the applicant under 42 U.S.C. § 262(*l*)(3), injunctive relief may be granted to prevent such infringement, while damages or other monetary relief may only be awarded if there has been commercial manufacture, use, offer to sell, or sale within the United States of an infringing product. Other than attorney fees, these are "the only remedies which may be granted by a court for [infringement of such a patent]." 35 U.S.C. § 271(e)(4)(B)-(D). Where, however, the infringed patent appears on the parties' agreed-upon list of patents that should be subject to an infringement action, 42 U.S.C. § 262(*l*)(4), or their respective lists of such patents, 42 U.S.C. § 262(*l*)(5)—and the sponsor did not sue within the time frame prescribed in subsection (*l*), had its suit dismissed without prejudice, or did not prosecute its suit to judgment in good faith—the "sole and exclusive remedy" for infringement "shall be a reasonable royalty." 35 U.S.C. § 271(e)(6).

Together, 42 U.S.C. § 262(*l*) and 35 U.S.C. § 271(e) reflect an integrated scheme that provides consequences for the choice either party makes at each step of subsection (*l*)'s information exchange to carry on the process, or end it and allow patent litigation to commence. At one step in this series of tradeoffs, for example, the applicant has sixty days to respond to a list of patents the sponsor flagged in the prior step as potential grounds for an infringement suit. The applicant, according to 42 U.S.C. § 262(*l*)(3)(B)(ii), must provide the factual and legal basis for its beliefs that any patents flagged by the sponsor are invalid, unenforceable, or not infringed by its biosimilar. If the applicant does not complete this step, however, the sponsor may bring a declaratory judgment action for any patents it flagged in the prior step. 42 U.S.C. § 262(*l*)(9)(B). Conclusion of the process yields a list of patents on which a sponsor may bring suit within thirty days. 42 U.S.C. § 262(*l*)(6). Should the sponsor elect not to do so, it may collect only a reasonable royalty. 35 U.S.C. § 271(e)(6)(A). Thus, to continue the process or to terminate it confers advantages and disadvantages the parties must weigh at each step.

B. Procedural Background

Since 1991, Amgen has produced and marketed the biologic product filgrastim under the brand-name Neupogen as a result of the FDA's approval of Amgen's application for a license to market the product pursuant to BLA No. 103353. Neupogen was originally approved for decreasing the incidence of infection, as

manifested by febrile neutropenia, in patients with nonmyeloid malignancies receiving myelosuppressive anticancer drugs associated with a significant incidence of severe neutropenia with fever. The FDA subsequently approved additional therapeutic indications for the drug, such as aiding faster engraftment and recovery for bone marrow transplant patients.

On July 7, 2014, Sandoz received notice that the FDA had accepted for review its BLA for approval of a biosimilar filgrastim product under subsection (k). The next day, it mailed a letter to Amgen offering to share a copy of its BLA under the protection of a proposed Offer of Conditional Access; notifying Amgen that it believed it would receive FDA approval in the first or second quarter of 2015; and stating its intent to market its biosimilar product immediately thereafter. Sandoz sent Amgen a second letter on July 25 again offering conditional access to its BLA. It also asserted therein that the BPCIA entitled it to opt out of subsection (*l*)'s procedures, and that Amgen could instead procure information via an infringement action. Amgen, it appears, declined both offers to view Sandoz's biosimilarity BLA under Sandoz's proposed terms. Only after a protracted dispute did the parties, on February 9, 2015, enter a stipulated protective order providing Amgen protected access to Sandoz's BLA and related application materials. They did not engage in any further patent information exchanges.

Amgen initiated this action on October 24, 2014, asserting claims of (1) unlawful competition under Cal.

Bus. & Prof. Code § 17200 et seq. based on two alleged violations of the BPCIA; (2) conversion; and (3) infringement of Amgen's '427 patent. According to Amgen, failure to comply with subsection (*l*)'s disclosure and negotiation procedures and its interpretation of subparagraph (*l*)(8)(A)'s 180-day notice requirement each comprise an unlawful business practice actionable under the UCL. In addition, Amgen contends, Sandoz's use of Amgen's FDA license for Neupogen in its biosimilarity BLA without abiding by subsection (*l*)'s procedures rises to an act of conversion.

Alongside its answer, the following month Sandoz asserted seven counterclaims seeking declaratory judgments in favor of its interpretation of the BPCIA, as well as non-infringement and invalidity of the '427 patent. Specifically, these counterclaims are for the following declaratory judgments: (1) subsection (k) applicants may elect not to provide their applications to the reference product sponsor, subject to the consequences set forth in 42 U.S.C. § 262(*l*)(9)(C); (2) the BPCIA does not provide for injunctive relief, restitution, or damages for failure of a subsection (k) applicant to share its BLA; (3) the BPCIA sets forth exclusive consequences for failure to comply with 42 U.S.C. § 262(*l*)'s disclosure, negotiation, and notification provisions; (4) the BPCIA renders remedies under UCL and conversion claims unlawful and/or preempted; (5) a reference product sponsor does not maintain exclusive possession or control over its

biologic product license; (6) noninfringement of the '427 patent; and (7) invalidity of the '427 patent.

Amgen now moves for partial judgment on the pleadings, or partial summary judgment in the alternative, as to the two bases in the BPCIA for its UCL claim, and for declaratory judgment barring Sandoz's sixth and seventh counterclaims. Sandoz cross-moves for partial judgment on the pleadings granting declaratory judgment in favor of its first through fifth counterclaims, for dismissal with prejudice of Amgen's UCL and conversion claims, and for denial of Amgen's motion.

III. LEGAL STANDARDS

While the Federal Circuit is the court of appeal for all cases raising claims under patent law, it defers to regional circuit courts on non-patent issues. *See* 28 U.S.C. 1338(a); *Holmes Group, Inc. v. Vornado Air Circulation Systems, Inc.*, 535 U.S. 826 (2002); *Research Corp. Techs. v. Microsoft Corp.*, 536 F.3d 1247, 1255 (Fed. Cir. 2008). Ninth Circuit law therefore governs the disposition of the parties' cross-motions.

Rule 12(c) of the Federal Rules of Civil Procedure provides that "[a]fter the pleadings are closed—but early enough not to delay trial—a party may move for judgment on the pleadings." Such a motion, like one brought under Rule 12(b)(6), challenges the "the legal sufficiency of the opposing party's pleadings." *Qwest Communications Corp. v. City of Berkeley*, 208 F.R.D. 288, 291 (N.D. Cal. 2002). Accordingly, "a plaintiff is

not entitled to judgment on the pleadings when the answer raises issues of fact that, if proved, would defeat recovery." *General Conference Corp. of Seventh-Day Adventists v. Seventh-Day Adventist Congregational Church*, 887 F.2d 228, 230 (9th Cir. 1989). A defendant's sufficient pleading of an applicable affirmative defense likewise will defeat a plaintiff's motion. *Id.* Regardless of what facts or affirmative defenses may be raised by an answer, however, a plaintiff's motion may not be granted absent a showing that he or she "is entitled to judgment as a matter of law." *Hal Roach Studios, Inc. v. Richard Feiner & Co., Inc.*, 896 F.2d 1542, 1550 (9th Cir. 1989).

Rule 56(a) of the Federal Rules of Civil Procedure provides that a "court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." The party who seeks summary judgment bears the initial responsibility of identifying the absence of a genuine issue of material fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). If the moving party satisfies this initial burden, it shifts to the non-moving party to present specific facts showing that there is a genuine issue for trial. *Celotex*, 477 U.S. at 324. "Only disputes over facts that might affect the outcome of the suit under governing law" are material. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). A genuine issue exists if the non-moving party presents evidence from which a reasonable factfinder, viewing the evidence

in the light most favorable to that party, could resolve the material issue in his or her favor. *Id.* at 248-49.

IV. DISCUSSION

As noted above, this dispute hinges on the interpretation of two portions of subsection 42 U.S.C. § 262(*l*) of the BCPIA. According to Amgen, Sandoz acted unlawfully because it (1) failed to comply with subsection (*l*)'s disclosure and negotiation procedures; and (2) intends to market its biosimilar immediately upon receiving FDA approval, rather than waiting until at least 180 days thereafter. These actions, Amgen avers, constitute the predicate wrongful behavior to sustain its claims under the UCL. Sandoz also committed conversion, avers Amgen, by making use of Amgen's FDA license for Neupogen in its biosimilarity BLA.[4]

Sandoz contends its actions have comported with the letter and spirit of the BPCIA, necessitating, therefore, the denial of Amgen's motion and dismissal of its UCL and conversion claims. As the analysis

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[4] While Amgen contended at oral argument that the BPCIA enables a private right of action from which its suit against Sandoz could, alternatively, have arisen, this set of motions does not properly raise that issue and it, accordingly, will not be addressed. Amgen is left with the untenable argument that Congress intended not a self-contained statutory scheme under the BPCIA, but rather contemplated a hunt by reference product sponsors through the laws of the fifty states to find a predicate by which to litigate a claimed BPCIA violation.

below demonstrates, Sandoz's reading of the statute is the more coherent of the two, and merits granting, in part, Sandoz's motion.

The interpretation of a statute is a question of law whose answer begins with an examination of the plain meaning of the statute. *United States v. Gomez-Osorio*, 957 F.2d 636, 639 (9th Cir. 1992). Words not otherwise defined take on their ordinary, common meaning. The court must, however, read a statute's language in context and with regard to its role in the overall statutory framework, looking to legislative history as appropriate. *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000); *United States v. Morton*, 467 U.S. 822, 828 (1984). If the statutory language is unambiguous, and the statutory scheme is coherent and consistent, that should mark the end of a court's interpretative inquiry. *Miranda v. Anchondo*, 684 F.3d 844, 849 (9th Cir. 2012).

A. BPCIA: Disclosure and Negotiation Procedures

As noted above, Sandoz elected not to supply Amgen with a copy of its BLA and manufacturing process description within twenty days from notice that the FDA had accepted its application for review,[5]

[5] Whether Amgen effectively declined access to Sandoz's BLA within these twenty days pursuant to Sandoz's July 2014 letters is a factual matter disputed by the parties, and is not at issue here.

and to engage in subsection (*l*)'s subsequent series of disclosures and negotiations regarding potential patent disputes. These acts, Amgen avers, amount to unlawful transgressions of mandatory requirements for subsection (k) applicants set forth in 42 U.S.C. § 262(*l*)(2)-(8). Indeed, these paragraphs repeatedly use the word "shall" to describe the parties' obligations under its prescribed procedures. Subparagraph (*l*)(9)(B) moreover characterizes lack of compliance as a "fail[ure] to provide the application and information required."

While such phrasing lends support to Amgen's reading, Sandoz's overall interpretation of the statute's plain language is more persuasive. While Amgen correctly notes that subsection (*l*) uses the word "may" in certain paragraphs, thereby suggesting that the use of "shall" in others implies an action is required, several countervailing factors reflect otherwise. First, that an action "shall" be taken does not imply it is mandatory in all contexts. It is fair to read subsection (*l*) to demand that, if both parties wish to take advantage of its disclosure procedures, then they "shall" follow the prescribed procedures; in other words, these procedures are "required" where the parties elect to take advantage of their benefits, and may be taken away when parties "fail."

That compliance allows an applicant to enjoy a temporary safe harbor from litigation and, potentially, to resolve or narrow patent disputes outside court proceedings, bolsters this reading. Subparagraphs (*l*) (9)(B) and (C) contemplate the scenario in

which an applicant does not comply at all with disclosure procedures, or fails to follow through after having begun the process. They allow the reference product sponsor to commence patent litigation immediately in either instance—removing (or precluding) availability to the applicant of a litigation safe harbor. Congress took the additional step in the BPCIA to amend 35 U.S.C. § 271(e) to add that an applicant's failure to disclose information regarding a potentially infringed patent under subsection (*l*)'s requirements is immediately actionable, making it clear that such a dispute is ripe for adjudication.

Such an interpretation would not be wholly without precedent; other district courts faced with a similar question have found that failure to comply with a provision containing "shall" was not unlawful, where the statute contemplated and provided for such a scenario. See *County of Ramsey v. MERSCORP Holdings, Inc.*, 962 F. Supp. 2d 1082, 1087 (D. Minn. 2013), *aff'd*, 776 F.3d 947 (8th Cir. 2014) (finding a statute stating that "[e]very conveyance of real estate shall be recorded" and that "every such conveyance not so recorded shall be void" was not mandatory because the statutory language "specifically contemplate[d] that not all conveyances will be recorded and outlines the consequence of failing to do so.")

Further, while Amgen contends persuasively that use of subsection (*l*)'s procedures can serve important public interests, including potential reduction of patent litigation and protection for innovators, nowhere does the statute evidence Congressional intent to

enhance innovators' substantive rights. In contrast to numerous other federal civil statutes which offer a claim for relief and specify remedies, here Congress did more than remain silent—it expressly directed reference product sponsors to commence patent infringement litigation in the event of an applicant's non-compliance. Even in subsection (*l*) itself, subparagraph (*l*)(8)(B) is clear in providing the remedy of a preliminary injunction for failure to give the 180-day notice required in (*l*)(8)(A). It is therefore evident that Congress intended merely to encourage use of the statute's dispute resolution process in favor of litigation, where practicable, with the carrot of a safe harbor for applicants who otherwise would remain vulnerable to suit. The statute contains no stick to force compliance in all instances, and Amgen does not identify any basis to impute one.

Indeed Sandoz's decision not to comply with subsection (*l*) reflects how the statute's overall scheme operates to promote expedient resolution of patent disputes. Compliance with the disclosure process affords an applicant many benefits: it allows the applicant to preview which patents the reference product sponsor believes are valid and infringed, assess related factual and legal support, and exercise some control over which patents are litigated and when. An applicant with a high (or unknown) risk of liability for infringement could benefit considerably from this process: it would be able to undergo the information exchange while protected by the statute's safe harbor from litigation, and if necessary, delay its product

launch to protect the investment it made in developing its biosimilar.

On the other hand, subsection (*l*) lays out a process that could take up to 230 days—just to commence patent litigation. An applicant who values expedience over risk mitigation may believe that the disclosure and negotiation process would introduce needless communications and delay. Such an applicant may have good reason to believe that no unexpired relevant patents relate to its biosimilar, and that it is likely to prevail if challenged with an infringement suit. The applicant may, in such an instance, opt to forego its ability to bring certain types of declaratory actions and receive information about potentially relevant patents from the reference product sponsor, and instead commence litigation immediately.

Perhaps confident in its limited exposure to liability and eager to resolve patent disputes so as not to face delays to market entry, Sandoz opted to invite a suit from Amgen soon after filing its BLA with the FDA.[6] Had the parties followed subsection (*l*)'s

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[6] While Amgen contends that the path chosen by Sandoz enables biosimilar producers to evade liability for patent infringement because biosimilar producers may keep reference product sponsors in the dark about their biosimilarity BLAs and plans to take their products to market, the 180-day notice requirement addressed below mitigates such concerns. With six months' advance notice of a biosimilar producer's intent to commence sales, a reference product sponsor who believes it may have an infringement claim can file suit to access the biosimilarity BLA, manufacturing process, and other relevant information via discovery—as

(Continued on following page)

disclosure and negotiation procedures, it is unlikely the present infringement action—filed in October 2014—would have even commenced until mid-March 2015, given the 230-day timeline over which subsection (*l*)'s procedures are designed to unfold. Sandoz therefore traded in the chance to narrow the scope of potential litigation with Amgen through subsection (*l*)'s steps, in exchange for the expediency of an immediate lawsuit. The BPCIA's plain language and overall statutory scheme support a reading that renders this decision entirely permissible.

B. BPCIA: One Hundred Eighty Days' Notice Prior to First Commercial Marketing

The most reasonable interpretation of paragraph (*l*)(8) of 42 U.S.C. § 262 also favors Sandoz. As noted above, this provision dictates that an applicant "shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k)." 42 U.S.C. § 262(*l*)(8)(A). Upon receiving such notice, the reference product sponsor may seek a court order enjoining such market entry until a court can decide issues of patent validity or infringement. 42 U.S.C. § 262(*l*)(8)(B). It may also

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in any other typical instance of potential infringement. While Amgen may have preferred that Sandoz share this information voluntarily, the BPCIA rendered it Sandoz's choice to make.

initiate a declaratory judgment action. 42 U.S.C. § 262(*l*)(9)(B).

Amgen makes too much of the phrase quoted above from subparagraph (*l*)(8)(A). It argues that the word "licensed," a past tense verb, means an applicant may not give the required 180-day notice to the reference product sponsor until *after* the FDA has granted approval of biosimilarity—resulting in a mandatory 180-day post-FDA approval waiting period prior to biosimilar market entry. Amgen draws support for this reading from Congress's use in other paragraphs of the statute of the phrase "subject of an application under subsection (k)" to refer to biosimilars. *See, e.g.*, 42 U.S.C. § 262(i)(2). Congress employs the distinction between the two phrasings, asserts Amgen, to signal whether it intends a particular provision to refer to a biosimilar before or after it has received FDA approval. Amgen contends that the only logical conclusion, therefore, is that because (*l*)(8)(A) refers not to the "subject of an application," but rather a "licensed" product, FDA approval must be a condition precedent to valid notice.

Amgen's attempt to bolster this interpretation by referencing a prior decision of this district, *Sandoz Inc. v. Amgen Inc.*, No. C-13-2904, 2013 WL 6000069, at *2 (N.D. Cal. Nov. 12, 2013), has little effect. In that case, Sandoz sued to obtain a declaratory judgment that two patents were invalid, unenforceable and would not be infringed if Sandoz used, offered to sell, sold, or imported a drug product "biosimilar" to Amgen's etanercept product Enbrel. Finding for

Amgen on Article III standing grounds, the court stated merely in passing that, in addition, Sandoz could not obtain a declaratory judgment prior to filing an FDA biosimilarity application according to the procedures set forth in 42 U.S.C. § 262(*l*). While Sandoz contended that its suit complied with section 262(*l*), which permits actions for declaratory judgment once a manufacturer of a licensed biosimilar has provided notice of commercial marketing, the district court—looking only to the language of the statute itself—wrote that "as a matter of law, [Sandoz] cannot have provided a [such notice] because . . . its [biosimilar] product is not 'licensed under subsection (k).'" *Id.* The Federal Circuit affirmed the district court's ruling on standing grounds, but expressly declined to address its BPCIA interpretation, which had not been briefed for the district court and was not dispositive in its ruling. This prior case, therefore, has little persuasive authority over the present dispute.

Indeed the more persuasive interpretation accounts for the fact that FDA approval must precede market entry. It would be nonsensical for subparagraph (*l*)(8)(A) to refer to a biosimilar as the subject of a subsection (k) application because upon its "first commercial marketing" a biosimilar must, in all instances, be a "licensed" product. "Before" modifies "first commercial marketing"; "licensed" refers only to "biological product"—not the appropriate time for notice.

Even more problematic with Amgen's reading is the impact it would have on the overall statutory

scheme. Because the FDA cannot license a biosimilar until twelve years after approval of a reference product, Amgen's reading would tack an unconditional extra six months of market exclusivity onto the twelve years reference product sponsors already enjoy under 42 U.S.C. § 262(k)(7)(A).[7] Had Congress intended to make the exclusivity period twelve and one-half years, it could not have chosen a more convoluted method of doing so. Moreover, Congress presumably could have been far more explicit had it intended for infringement suits to commence only once a biosimilar receives FDA approval. It was, therefore, not wrongful for Sandoz to give Amgen its 180 days' notice prior to first commercial marketing pursuant to subparagraph (*l*)(8)(A) in July 2014, in advance of receiving FDA approval.[8]

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[7] Amgen contends that because the FDA approval process may entail modifications to a biosimilar's properties or manufacturing process, allowing applicants to give 180-day notice prior to FDA approval would burden sponsors with the unfair task of having to aim infringement claims at a moving target. While this statutory construction may indeed disadvantage sponsors in some respects, such policy considerations are for Congress, not the courts, to address.

[8] In addition, had Sandoz failed to do so, it would be subject only to the consequences prescribed in 42 U.S.C. § 262(*l*)(9)(B)—an action for declaratory judgment regarding patent infringement, viability, or enforceability.

C. Amgen's State-Law Claims for Unlawful Business Practices and Conversion

Because Sandoz's actions did not violate the BPCIA, it has committed no unlawful or wrongful predicate act to sustain Amgen's claims under the UCL and for conversion. A plaintiff may proceed under the UCL on three possible theories. First, "unlawful" conduct that violates another law is independently actionable under § 17200. *Cel-Tech Commc'ns, Inc. v. Los Angeles Cellular Telephone Co.*, 20 Cal. 4th 163, 180 (1999). Alternatively, a plaintiff may plead that defendants' conduct is "unfair" within the meaning of the several standards developed by the courts. *Id.* at 186-87, 83 (finding of unfairness must be "tethered to some legislatively declared policy or proof of some actual or threatened impact on competition"); *Lozano v. AT & T Wireless Servs., Inc.*, 504 F.3d 718, 736 (9th Cir. 2007) (requiring, in consumer cases, "unfairness be tied to a 'legislatively declared' policy" or that the harm to consumers outweighs the utility of the challenged conduct). Finally, a plaintiff may challenge "fraudulent" conduct by showing that "members of the public are likely to be deceived" by the challenged business acts or practices. *In re Tobacco II Cases*, 46 Cal. 4th 298, 312 (2009); *Daugherty v. Am. Honda Motor Co., Inc.*, 144 Cal. App. 4th 824, 838 (2006) (elements of violation of UCL for "fraudulent" business practices are distinct from common law fraud). Amgen tethers its UCL claim to only the first theory, averring that Sandoz behaved unlawfully by violating both subsection (*l*)'s disclosure and negotiation procedures and

paragraph (*l*)(8)(A)'s 180-day notice requirement. As shown above, however, Sandoz's actions are within its rights and subject only to the consequences contemplated in the BPCIA. Because Amgen has not shown that Sandoz violated any provision of law, its UCL claim fails.

Amgen further alleges that Sandoz's reliance on Amgen's FDA license for Neupogen in its subsection (k) application constitutes conversion. To sustain a claim for conversion, a plaintiff must demonstrate (1) the plaintiff's ownership or right to possession of the property; (2) the defendant's conversion by a wrongful act or disposition of property rights; and (3) damages. *Burlesci v. Petersen,* 68 Cal. App. 4th 1062 (1998).

Sandoz's "wrongful act," alleges Amgen, was making use of Amgen's FDA license for Neupogen without complying with subsection (*l*)'s disclosure and negotiation procedures. Yet the BPCIA expressly contemplates that a subsection (k) applicant will rely on the reference product's license and other publicly available safety and efficacy information about the reference product. Indeed, as Sandoz's decision to forego the benefits of subsection (*l*)'s disclosure and negotiation procedures and instead open itself up to immediate suit for patent infringement was entirely permissible under 42 U.S.C. § 262, Sandoz has committed no wrongful act. The effect of Amgen's position—that Congress intended for sponsors to resort to state laws to enforce mandatory provisions in a federal statute and collect remedies for their violation, in

addition to exacting the consequences written expressly into the legislation itself—is unworkable. Amgen therefore cannot maintain a claim for either unlawful business practices or conversion, and both claims are dismissed with prejudice pursuant to Sandoz's motion.

D. Sandoz's Counterclaims for Patent Noninfringement and Invalidity

Amgen contends that 42 U.S.C. § 262(*l*)(9)(C) bars the counterclaims for declaratory judgment of noninfringement and invalidity Sandoz alleges in response to Amgen's averment that Sandoz infringed its '427 patent. Subparagraph (*l*)(9)(C) states that where, as here, an applicant has not provided its BLA and manufacturing process information to the reference product sponsor, "the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of title 28, United States Code, for a declaration of infringement, validity, or enforceability of any patent that claims the biological product or a use of the biological product." According to Amgen, this provision prohibits Sandoz, a subsection (k) applicant who has not provided its BLA and manufacturing process information to its sponsor, from raising its counterclaims for declaratory judgment regarding the '427 patent.

Asserting a counterclaim is not the equivalent of commencing a lawsuit. *See Alexander v. Hillman*, 296 U.S. 222, 241 (1935). The BPCIA addresses only an

applicant's ability to "bring an action," not to assert a counterclaim if placed in a position to defend against an infringement suit. Furthermore, as Sandoz's counterclaims arise from the same transaction or occurrence that is the subject of Amgen's claim—the validity and relevance of Amgen's '427 patent—they are compulsory, and would be waived if not asserted. Barring such claims in particular raises "real due process concerns." *See U.S. ex rel. Miller v. Bill Harbert Intern. Const., Inc.*, 505 F. Supp. 2d 20, 26 (D.D.C. 2007). Sandoz's sixth and seventh counterclaims regarding Amgen's '427 patent are, therefore, not barred by the BPCIA.

E. Amgen's Motion for Preliminary Injunction

Amgen has claimed it is entitled to both preliminary relief in advance of a decision on the merits, and, in the event of a decision in its favor, an injunctive remedy placing the parties where they would have stood had Sandoz fully complied with the BPCIA as Amgen interprets it. To obtain a preliminary injunction, a plaintiff must establish a likelihood of success on the merits; that he or she is likely to suffer irreparable harm in the absence of preliminary relief; that the balance of equities tips in his or her favor; and that an injunction would serve the public interest. *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008). The Federal Circuit applies this standard in reviewing the grant or denial of an injunction where the issues at play are unique to patent law. Where they are not, it applies the law of the regional

circuit (here, the Ninth Circuit). *See Allergan, Inc. v. Athena Cosmetics, Inc.*, 738 F.3d 1350, 1354 (Fed. Cir. 2013). The Ninth Circuit has clarified that courts in this Circuit should evaluate the likelihood of success on a "sliding scale." *Alliance for Wild Rockies v. Cottrell*, 632 F.3d 1127, 1134 (9th Cir. 2011) ("[T]he 'serious questions' version of the sliding scale test for preliminary injunctions remains viable after the Supreme Court's decision in *Winter*."). According to this test, "[a] preliminary injunction is appropriate when a plaintiff demonstrates . . . that serious questions going to the merits were raised and the balance of hardships tips sharply in the plaintiff's favor," provided, of course, that "plaintiffs must also satisfy the other [*Winter*] factors" including the likelihood of irreparable harm. *Id.* at 1135.

The parties disagree as to which standard is appropriate here. Yet because it cannot demonstrate serious questions as to the merits, let alone a likelihood of success, Amgen is foreclosed from injunctive relief under either formulation of the test for injunctive relief.

Indeed, the analysis above resolves in Sandoz's favor the merits as to the issues raised in the parties' cross-motions. Neither Sandoz's failure to supply its BLA and manufacturing process information within twenty days of learning the FDA had accepted its application for approval and subsequent decision to forego subsection (*l*)'s disclosure and negotiation

procedures,[9] nor its intention to proceed to market by giving 180-day in advance of FDA approval, constitutes wrongful or unlawful behavior. As Amgen has failed to show otherwise, neither Amgen's UCL claim nor its conversion claim is, therefore, viable; and it has yet to proceed on its remaining claim for patent infringement.

Amgen furthermore does not carry its burden to demonstrate that irreparable harm will result in the absence of injunctive relief. Amgen argues market entry of Sandoz's biosimilar filgrastim product will cause it irreparable harm in several respects, specifically by: (1) delaying or precluding Amgen (through its sales of biosimilar filgrastim and diversion of revenue from Amgen) from undertaking research and development for new drugs and potentially causing Amgen to lose staff and scientists; (2) diverting Amgen sales representatives' energy from selling new products to competing with Sandoz for filgrastim market share; (3) causing Amgen to drop the price of Neupogen to remain competitive; and (4) damaging Amgen's customer relationships and goodwill in the event that the Court compels Sandoz to remove its product from the market, thereby prompting Amgen to enforce the order or raise its prices to where they were prior to Sandoz's market entry.

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[9] Even were the BPCIA to render unlawful an applicant's failure to supply its BLA and manufacturing process information to the reference product sponsor within twenty days, whether Sandoz made such information available to Amgen in a timely manner is a factual dispute between the parties that need not be reached here.

Not only are such harms at best highly speculative; they are based on the as-yet unproven premise that Sandoz has infringed a valid patent belonging to Amgen. While Amgen has averred infringement of its '427 patent and argues that Sandoz's biosimilar filgrastim has the potential to infringe some four hundred more, *see* Declaration of Stuart Watt, it has not raised these contentions for a disposition at this juncture. It must, therefore, be assumed that no such infringement has occurred. As the twelve-year exclusivity period for Neupogen long ago expired, there exists no substantive bar to market entry for Sandoz's biosimilar filgrastim—and, consequently, no basis on which Amgen is entitled to injunctive relief or other remedies for disadvantages it may suffer due to market competition from Sandoz.

V. CONCLUSION

For the all of the aforementioned reasons, Amgen's motions for partial judgment on the pleadings or partial summary judgment in the alternative, and for preliminary injunction, are denied. Its claims under the UCL and for conversion are, furthermore, dismissed with prejudice.

Insofar as the above interpretation of the BPCIA is consistent with Sandoz's first through fifth counterclaims, judgment is hereby entered in Sandoz's favor. The BPCIA renders permissible a subsection (k) applicant's decision not to provide its BLA and/or manufacturing information to the reference product sponsor, subject only to the consequences set forth in

42 U.S.C. § 262(*l*)(9)(C). Such a decision alone does not offer a basis for the sponsor to obtain injunctive relief, restitution, or damages against the applicant; indeed, 42 U.S.C. § 262(*l*)(9) sets out the exclusive consequences for an applicant who elects not to provide its BLA and/or manufacturing information, or participate in any aspect of subsection (*l*)'s disclosure and negotiation process. As the BPCIA contemplates that a subsection (k) applicant will use the reference product sponsor's FDA license, and does not declare it unlawful for the applicant to do so without participating in subsection (*l*)'s disclosure and negotiation process, there exists no predicate wrongful act on which to base Amgen's conversion claim.[10] In addition, the BPCIA poses no bar to Sandoz's sixth and seventh counterclaims for patent noninfringement and invalidity as to Amgen's '427 patent.

IT IS SO ORDERED.

Dated: March 19, 2015

/s/ Richard Seeborg
RICHARD SEEBORG
United States District Judge

[10] Whether a sponsor otherwise maintains some exclusive property rights over an FDA license obtained for a biologic product is beyond the scope of this disposition.

APPENDIX C

NOTE: This order is nonprecedential.

United States Court of Appeals for the Federal Circuit

AMGEN INC., AMGEN MANUFACTURING LIMITED,
Plaintiffs-Appellants

v.

SANDOZ INC.,
Defendant-Appellee

2015-1499

Appeal from the United States District Court for the Northern District of California in No. 3:14-cv-04741-RS, Judge Richard Seeborg.

ON PETITION FOR REHEARING EN BANC

Before PROST, *Chief Judge*, NEWMAN, LOURIE, DYK, MOORE, O'MALLEY, REYNA, WALLACH, TARANTO, CHEN, HUGHES, and STOLL, *Circuit Judges*.

PER CURIAM.

ORDER

Appellants Amgen Inc. and Amgen Manufacturing Limited filed a petition for rehearing en banc. A response thereto was invited by the court and filed by Appellee Sandoz Inc. A petition for rehearing en banc was filed by Sandoz Inc., and a response was invited by the court and filed by appellants Amgen Inc. and Amgen Manufacturing Limited. The petitions for rehearing were first referred to the panel that heard the appeal, and thereafter, to the circuit judges who are in regular active service.

Upon consideration thereof,

IT IS ORDERED THAT:

The petitions for panel rehearing are denied.

The petitions for rehearing en banc are denied.

The mandate of the court will issue on October 23, 2015.

FOR THE COURT

October 16, 2015
Date

/s/ Daniel E. O'Toole
Daniel E. O'Toole
Clerk of Court

APPENDIX D

Public Law 111-148
111th Congress

An Act

Entitled The Patient
Protection and Affordable Care Act.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

* * *

TITLE VII—IMPROVING ACCESS TO INNOVATIVE MEDICAL THERAPIES

Subtitle A—Biologics Price Competition and Innovation

SEC. 7001. SHORT TITLE.

(a) IN GENERAL.—This subtitle may be cited as the "Biologics Price Competition and Innovation Act of 2009".

(b) SENSE OF THE SENATE.—It is the sense of the Senate that a biosimilars pathway balancing innovation and consumer interests should be established.

SEC. 7002. APPROVAL PATHWAY FOR BIOSIMILAR BIOLOGICAL PRODUCTS.

(a) LICENSURE OF BIOLOGICAL PRODUCTS AS BIOSIMILAR OR INTERCHANGEABLE.—Section 351 of the

Public Health Service Act (42 U.S.C. 262) is amended—

(1) in subsection (a)(1)(A), by inserting "under this subsection or subsection (k)" after "biologics license"; and

(2) by adding at the end the following:

"(k) LICENSURE OF BIOLOGICAL PRODUCTS AS BIOSIMILAR OR INTERCHANGEABLE.—

"(1) IN GENERAL.—Any person may submit an application for licensure of a biological product under this subsection.

"(2) CONTENT.—

"(A) IN GENERAL.—

"(i) REQUIRED INFORMATION.—An application submitted under this subsection shall include information demonstrating that—

"(I) the biological product is biosimilar to a reference product based upon data derived from—

"(aa) analytical studies that demonstrate that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components;

"(bb) animal studies (including the assessment of toxicity); and

"(cc) a clinical study or studies (including the assessment of immunogenicity and pharmacokinetics or pharmacodynamics) that are sufficient to demonstrate safety, purity, and potency in 1 or more appropriate conditions of use for which the reference product is licensed and intended to be used and for which licensure is sought for the biological product;

"(II) the biological product and reference product utilize the same mechanism or mechanisms of action for the condition or conditions of use prescribed, recommended, or suggested in the proposed labeling, but only to the extent the mechanism or mechanisms of action are known for the reference product;

"(III) the condition or conditions of use prescribed, recommended, or suggested in the labeling proposed for the biological product have been previously approved for the reference product;

"(IV) the route of administration, the dosage form, and the strength of the biological product are the same as those of the reference product; and

"(V) the facility in which the biological product is manufactured, processed, packed, or held meets standards designed to assure that the biological product continues to be safe, pure, and potent.

"(ii) DETERMINATION BY SECRETARY.—The Secretary may determine, in the Secretary's discretion, that an element described in clause (i)(I) is unnecessary in an application submitted under this subsection.

"(iii) ADDITIONAL INFORMATION.—An application submitted under this subsection—

"(I) shall include publicly-available information regarding the Secretary's previous determination that the reference product is safe, pure, and potent; and

"(II) may include any additional information in support of the application, including publicly-available information with respect to the reference product or another biological product.

"(B) INTERCHANGEABILITY.—An application (or a supplement to an application) submitted under this subsection may include information demonstrating that the biological product meets the standards described in paragraph (4).

"(3) EVALUATION BY SECRETARY.—Upon review of an application (or a supplement to an application) submitted under this subsection, the Secretary shall license the biological product under this subsection if—

"(A) the Secretary determines that the information submitted in the application (or the supplement) is sufficient to show that the biological product—

"(i) is biosimilar to the reference product; or

"(ii) meets the standards described in paragraph (4), and therefore is interchangeable with the reference product; and

"(B) the applicant (or other appropriate person) consents to the inspection of the facility that is the subject of the application, in accordance with subsection (c).

"(4) SAFETY STANDARDS FOR DETERMINING INTERCHANGEABILITY.—Upon review of an application submitted under this subsection or any supplement to such application, the Secretary shall determine the biological product to be interchangeable with the reference product if the Secretary determines that the information submitted in the application (or a supplement to such application) is sufficient to show that—

"(A) the biological product—

"(i) is biosimilar to the reference product; and

"(ii) can be expected to produce the same clinical result as the reference product in any given patient; and

"(B) for a biological product that is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch.

"(5) GENERAL RULES.—

"(A) ONE REFERENCE PRODUCT PER APPLICATION.—A biological product, in an application submitted under this subsection, may not be evaluated against more than 1 reference product.

"(B) REVIEW.—An application submitted under this subsection shall be reviewed by the division within the Food and Drug Administration that is responsible for the review and approval of the application under which the reference product is licensed.

"(C) RISK EVALUATION AND MITIGATION STRATEGIES.—The authority of the Secretary with respect to risk evaluation and mitigation strategies under the Federal Food, Drug, and Cosmetic Act shall apply to biological products licensed under this subsection in the same manner as such authority applies to biological products licensed under subsection (a).

"(6) EXCLUSIVITY FOR FIRST INTERCHANGEABLE BIOLOGICAL PRODUCT.—Upon review of an application submitted under this subsection relying on the same reference product for which a prior biological product has received a determination of interchangeability for any condition of use, the Secretary shall not make a determination under paragraph (4) that the second or subsequent biological product is interchangeable for any condition of use until the earlier of—

"(A) 1 year after the first commercial marketing of the first interchangeable biosimilar biological product to be approved as interchangeable for that reference product;

"(B) 18 months after—

"(i) a final court decision on all patents in suit in an action instituted under subsection (l)(6) against the applicant that submitted the application for the first approved interchangeable biosimilar biological product; or

"(ii) the dismissal with or without prejudice of an action instituted under subsection (l)(6) against the applicant that submitted the application for the first approved interchangeable biosimilar biological product; or

"(C)(i) 42 months after approval of the first interchangeable biosimilar biological product if the applicant that submitted such application has been sued under subsection

(l)(6) and such litigation is still ongoing within such 42-month period; or

"(ii) 18 months after approval of the first interchangeable biosimilar biological product if the applicant that submitted such application has not been sued under subsection (l)(6).

For purposes of this paragraph, the term 'final court decision' means a final decision of a court from which no appeal (other than a petition to the United States Supreme Court for a writ of certiorari) has been or can be taken.

"(7) EXCLUSIVITY FOR REFERENCE PRODUCT.—

"(A) EFFECTIVE DATE OF BIOSIMILAR APPLICATION APPROVAL.—Approval of an application under this subsection may not be made effective by the Secretary until the date that is 12 years after the date on which the reference product was first licensed under subsection (a).

"(B) FILING PERIOD.—An application under this subsection may not be submitted to the Secretary until the date that is 4 years after the date on which the reference product was first licensed under subsection (a).

"(C) FIRST LICENSURE.—Subparagraphs (A) and (B) shall not apply to a license for or approval of—

"(i) a supplement for the biological product that is the reference product; or

"(ii) a subsequent application filed by the same sponsor or manufacturer of the biological product that is the reference product (or a licensor, predecessor in interest, or other related entity) for—

"(I) a change (not including a modification to the structure of the biological product) that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device, or strength; or

"(II) a modification to the structure of the biological product that does not result in a change in safety, purity, or potency.

"(8) GUIDANCE DOCUMENTS.—

"(A) IN GENERAL.—The Secretary may, after opportunity for public comment, issue guidance in accordance, except as provided in subparagraph (B)(i), with section 701(h) of the Federal Food, Drug, and Cosmetic Act with respect to the licensure of a biological product under this subsection. Any such guidance may be general or specific.

"(B) PUBLIC COMMENT.—

"(i) IN GENERAL.—The Secretary shall provide the public an opportunity to comment on any proposed guidance issued under subparagraph (A) before issuing final guidance.

"(ii) INPUT REGARDING MOST VALUABLE GUIDANCE.—The Secretary shall establish a process through which the public may provide the Secretary with input regarding priorities for issuing guidance.

"(C) NO REQUIREMENT FOR APPLICATION CONSIDERATION.—The issuance (or non-issuance) of guidance under subparagraph (A) shall not preclude the review of, or action on, an application submitted under this subsection.

"(D) REQUIREMENT FOR PRODUCT CLASS-SPECIFIC GUIDANCE.—If the Secretary issues product class-specific guidance under subparagraph (A), such guidance shall include a description of—

"(i) the criteria that the Secretary will use to determine whether a biological product is highly similar to a reference product in such product class; and

"(ii) the criteria, if available, that the Secretary will use to determine whether a biological product meets the standards described in paragraph (4).

"(E) CERTAIN PRODUCT CLASSES.—

"(i) GUIDANCE.—The Secretary may indicate in a guidance document that the science and experience, as of the date of such guidance, with respect to a product or product class (not including any recombinant protein) does not allow

approval of an application for a license as provided under this subsection for such product or product class.

"(ii) MODIFICATION OR REVERSAL.—The Secretary may issue a subsequent guidance document under subparagraph (A) to modify or reverse a guidance document under clause (i).

"(iii) NO EFFECT ON ABILITY TO DENY LICENSE.—Clause (i) shall not be construed to require the Secretary to approve a product with respect to which the Secretary has not indicated in a guidance document that the science and experience, as described in clause (i), does not allow approval of such an application.

"(l) PATENTS.—

"(1) CONFIDENTIAL ACCESS TO SUBSECTION (k) APPLICATION.—

"(A) APPLICATION OF PARAGRAPH.—Unless otherwise agreed to by a person that submits an application under subsection (k) (referred to in this subsection as the 'subsection (k) applicant') and the sponsor of the application for the reference product (referred to in this subsection as the 'reference product sponsor'), the provisions of this paragraph shall apply to the exchange of information described in this subsection.

"(B) IN GENERAL.—

"(i) PROVISION OF CONFIDENTIAL INFORMATION.—When a subsection (k) applicant submits an application under subsection (k), such applicant shall provide to the persons described in clause (ii), subject to the terms of this paragraph, confidential access to the information required to be produced pursuant to paragraph (2) and any other information that the subsection (k) applicant determines, in its sole discretion, to be appropriate (referred to in this subsection as the 'confidential information').

"(ii) RECIPIENTS OF INFORMATION.—The persons described in this clause are the following:

"(I) OUTSIDE COUNSEL.—One or more attorneys designated by the reference product sponsor who are employees of an entity other than the reference product sponsor (referred to in this paragraph as the 'outside counsel'), provided that such attorneys do not engage, formally or informally, in patent prosecution relevant or related to the reference product.

"(II) IN-HOUSE COUNSEL.—One attorney that represents the reference product sponsor who is an employee of the reference product sponsor, provided that such attorney does not engage, formally or informally, in

patent prosecution relevant or related to the reference product.

"(iii) PATENT OWNER ACCESS.—A representative of the owner of a patent exclusively licensed to a reference product sponsor with respect to the reference product and who has retained a right to assert the patent or participate in litigation concerning the patent may be provided the confidential information, provided that the representative informs the reference product sponsor and the subsection (k) applicant of his or her agreement to be subject to the confidentiality provisions set forth in this paragraph, including those under clause (ii).

"(C) LIMITATION ON DISCLOSURE.—No person that receives confidential information pursuant to subparagraph (B) shall disclose any confidential information to any other person or entity, including the reference product sponsor employees, outside scientific consultants, or other outside counsel retained by the reference product sponsor, without the prior written consent of the subsection (k) applicant, which shall not be unreasonably withheld.

"(D) USE OF CONFIDENTIAL INFORMATION.—Confidential information shall be used for the sole and exclusive purpose of determining, with respect to each patent assigned to or exclusively licensed by the reference product sponsor, whether a claim of patent infringement could reasonably be asserted if the subsection (k) applicant engaged in the

manufacture, use, offering for sale, sale, or importation into the United States of the biological product that is the subject of the application under subsection (k).

"(E) OWNERSHIP OF CONFIDENTIAL INFORMATION.—The confidential information disclosed under this paragraph is, and shall remain, the property of the subsection (k) applicant. By providing the confidential information pursuant to this paragraph, the subsection (k) applicant does not provide the reference product sponsor or the outside counsel any interest in or license to use the confidential information, for purposes other than those specified in subparagraph (D).

"(F) EFFECT OF INFRINGEMENT ACTION.—In the event that the reference product sponsor files a patent infringement suit, the use of confidential information shall continue to be governed by the terms of this paragraph until such time as a court enters a protective order regarding the information. Upon entry of such order, the subsection (k) applicant may redesignate confidential information in accordance with the terms of that order. No confidential information shall be included in any publicly-available complaint or other pleading. In the event that the reference product sponsor does not file an infringement action by the date specified in paragraph (6), the reference product sponsor shall return or destroy all confidential information received under this paragraph, provided that if the reference product sponsor opts to destroy

such information, it will confirm destruction in writing to the subsection (k) applicant.

"(G) RULE OF CONSTRUCTION.—Nothing in this paragraph shall be construed—

"(i) as an admission by the subsection (k) applicant regarding the validity, enforceability, or infringement of any patent; or

"(ii) as an agreement or admission by the subsection (k) applicant with respect to the competency, relevance, or materiality of any confidential information.

"(H) EFFECT OF VIOLATION.—The disclosure of any confidential information in violation of this paragraph shall be deemed to cause the subsection (k) applicant to suffer irreparable harm for which there is no adequate legal remedy and the court shall consider immediate injunctive relief to be an appropriate and necessary remedy for any violation or threatened violation of this paragraph.

"(2) SUBSECTION (k) APPLICATION INFORMATION.—Not later than 20 days after the Secretary notifies the subsection (k) applicant that the application has been accepted for review, the subsection (k) applicant—

"(A) shall provide to the reference product sponsor a copy of the application submitted to the Secretary under subsection (k), and such other information that describes

the process or processes used to manufacture the biological product that is the subject of such application; and

"(B) may provide to the reference product sponsor additional information requested by or on behalf of the reference product sponsor.

"(3) LIST AND DESCRIPTION OF PATENTS.—

"(A) LIST BY REFERENCE PRODUCT SPONSOR.—Not later than 60 days after the receipt of the application and information under paragraph (2), the reference product sponsor shall provide to the subsection (k) applicant—

"(i) a list of patents for which the reference product sponsor believes a claim of patent infringement could reasonably be asserted by the reference product sponsor, or by a patent owner that has granted an exclusive license to the reference product sponsor with respect to the reference product, if a person not licensed by the reference product sponsor engaged in the making, using, offering to sell, selling, or importing into the United States of the biological product that is the subject of the subsection (k) application; and

"(ii) an identification of the patents on such list that the reference product sponsor would be prepared to license to the subsection (k) applicant.

"(B) LIST AND DESCRIPTION BY SUBSECTION (k) APPLICANT.—Not later than 60 days after receipt of the list under subparagraph (A), the subsection (k) applicant—

"(i) may provide to the reference product sponsor a list of patents to which the subsection (k) applicant believes a claim of patent infringement could reasonably be asserted by the reference product sponsor if a person not licensed by the reference product sponsor engaged in the making, using, offering to sell, selling, or importing into the United States of the biological product that is the subject of the subsection (k) application;

"(ii) shall provide to the reference product sponsor, with respect to each patent listed by the reference product sponsor under subparagraph (A) or listed by the subsection (k) applicant under clause (i)—

"(I) a detailed statement that describes, on a claim by claim basis, the factual and legal basis of the opinion of the subsection (k) applicant that such patent is invalid, unenforceable, or will not be infringed by the commercial marketing of the biological product that is the subject of the subsection (k) application; or

"(II) a statement that the subsection (k) applicant does not intend

to begin commercial marketing of the biological product before the date that such patent expires; and

"(iii) shall provide to the reference product sponsor a response regarding each patent identified by the reference product sponsor under subparagraph (A)(ii).

"(C) DESCRIPTION BY REFERENCE PRODUCT SPONSOR.—Not later than 60 days after receipt of the list and statement under subparagraph (B), the reference product sponsor shall provide to the subsection (k) applicant a detailed statement that describes, with respect to each patent described in subparagraph (B)(ii)(I), on a claim by claim basis, the factual and legal basis of the opinion of the reference product sponsor that such patent will be infringed by the commercial marketing of the biological product that is the subject of the subsection (k) application and a response to the statement concerning validity and enforceability provided under subparagraph (B)(ii)(I).

"(4) PATENT RESOLUTION NEGOTIATIONS.—

"(A) IN GENERAL.—After receipt by the subsection (k) applicant of the statement under paragraph (3)(C), the reference product sponsor and the subsection (k) applicant shall engage in good faith negotiations to agree on which, if any, patents listed under paragraph (3) by the subsection (k) applicant or the reference product sponsor shall be the

subject of an action for patent infringement under paragraph (6).

"(B) FAILURE TO REACH AGREEMENT.—If, within 15 days of beginning negotiations under subparagraph (A), the subsection (k) applicant and the reference product sponsor fail to agree on a final and complete list of which, if any, patents listed under paragraph (3) by the subsection (k) applicant or the reference product sponsor shall be the subject of an action for patent infringement under paragraph (6), the provisions of paragraph (5) shall apply to the parties.

"(5) PATENT RESOLUTION IF NO AGREEMENT.—

"(A) NUMBER OF PATENTS.—The subsection (k) applicant shall notify the reference product sponsor of the number of patents that such applicant will provide to the reference product sponsor under subparagraph (B)(i)(I).

"(B) EXCHANGE OF PATENT LISTS.—

"(i) IN GENERAL.—On a date agreed to by the subsection (k) applicant and the reference product sponsor, but in no case later than 5 days after the subsection (k) applicant notifies the reference product sponsor under subparagraph (A), the subsection (k) applicant and the reference product sponsor shall simultaneously exchange—

"(I) the list of patents that the subsection (k) applicant believes

should be the subject of an action for patent infringement under paragraph (6); and

"(II) the list of patents, in accordance with clause (ii), that the reference product sponsor believes should be the subject of an action for patent infringement under paragraph (6).

"(ii) NUMBER OF PATENTS LISTED BY REFERENCE PRODUCT SPONSOR.—

"(I) IN GENERAL.—Subject to subclause (II), the number of patents listed by the reference product sponsor under clause (i)(II) may not exceed the number of patents listed by the subsection (k) applicant under clause (i)(I).

"(II) EXCEPTION.—If a subsection (k) applicant does not list any patent under clause (i)(I), the reference product sponsor may list 1 patent under clause (i)(II).

"(6) IMMEDIATE PATENT INFRINGEMENT ACTION.—

"(A) ACTION IF AGREEMENT ON PATENT LIST.—If the subsection (k) applicant and the reference product sponsor agree on patents as described in paragraph (4), not later than 30 days after such agreement, the reference product sponsor shall bring an action for

patent infringement with respect to each such patent.

"(B) ACTION IF NO AGREEMENT ON PATENT LIST.—If the provisions of paragraph (5) apply to the parties as described in paragraph (4)(B), not later than 30 days after the exchange of lists under paragraph (5)(B), the reference product sponsor shall bring an action for patent infringement with respect to each patent that is included on such lists.

"(C) NOTIFICATION AND PUBLICATION OF COMPLAINT.—

"(i) NOTIFICATION TO SECRETARY.—Not later than 30 days after a complaint is served to a subsection (k) applicant in an action for patent infringement described under this paragraph, the subsection (k) applicant shall provide the Secretary with notice and a copy of such complaint.

"(ii) PUBLICATION BY SECRETARY.—The Secretary shall publish in the Federal Register notice of a complaint received under clause (i).

"(7) NEWLY ISSUED OR LICENSED PATENTS.—In the case of a patent that—

"(A) is issued to, or exclusively licensed by, the reference product sponsor after the date that the reference product sponsor provided the list to the subsection (k) applicant under paragraph (3)(A); and

"(B) the reference product sponsor reasonably believes that, due to the issuance of such patent, a claim of patent infringement could reasonably be asserted by the reference product sponsor if a person not licensed by the reference product sponsor engaged in the making, using, offering to sell, selling, or importing into the United States of the biological product that is the subject of the subsection (k) application,

not later than 30 days after such issuance or licensing, the reference product sponsor shall provide to the subsection (k) applicant a supplement to the list provided by the reference product sponsor under paragraph (3)(A) that includes such patent, not later than 30 days after such supplement is provided, the subsection (k) applicant shall provide a statement to the reference product sponsor in accordance with paragraph (3)(B), and such patent shall be subject to paragraph (8).

"(8) NOTICE OF COMMERCIAL MARKETING AND PRELIMINARY INJUNCTION.—

"(A) NOTICE OF COMMERCIAL MARKETING.—The subsection (k) applicant shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k).

"(B) PRELIMINARY INJUNCTION.—After receiving the notice under subparagraph (A) and before such date of the first commercial marketing of such biological product, the

reference product sponsor may seek a preliminary injunction prohibiting the subsection (k) applicant from engaging in the commercial manufacture or sale of such biological product until the court decides the issue of patent validity, enforcement, and infringement with respect to any patent that is—

"(i) included in the list provided by the reference product sponsor under paragraph (3)(A) or in the list provided by the subsection (k) applicant under paragraph (3)(B); and

"(ii) not included, as applicable, on—

"(I) the list of patents described in paragraph (4); or

"(II) the lists of patents described in paragraph (5)(B).

"(C) REASONABLE COOPERATION.—If the reference product sponsor has sought a preliminary injunction under subparagraph (B), the reference product sponsor and the subsection (k) applicant shall reasonably cooperate to expedite such further discovery as is needed in connection with the preliminary injunction motion.

"(9) LIMITATION ON DECLARATORY JUDGMENT ACTION.—

"(A) SUBSECTION (k) APPLICATION PROVIDED.—If a subsection (k) applicant provides the application and information required

under paragraph (2)(A), neither the reference product sponsor nor the subsection (k) applicant may, prior to the date notice is received under paragraph (8)(A), bring any action under section 2201 of title 28, United States Code, for a declaration of infringement, validity, or enforceability of any patent that is described in clauses (i) and (ii) of paragraph (8)(B).

"(B) SUBSEQUENT FAILURE TO ACT BY SUBSECTION (k) APPLICANT.—If a subsection (k) applicant fails to complete an action required of the subsection (k) applicant under paragraph (3)(B)(ii), paragraph (5), paragraph (6)(C)(i), paragraph (7), or paragraph (8)(A), the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of title 28, United States Code, for a declaration of infringement, validity, or enforceability of any patent included in the list described in paragraph (3)(A), including as provided under paragraph (7).

"(C) SUBSECTION (k) APPLICATION NOT PROVIDED.—If a subsection (k) applicant fails to provide the application and information required under paragraph (2)(A), the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of title 28, United States Code, for a declaration of infringement, validity, or enforceability of any patent that claims the biological product or a use of the biological product.".

(b) DEFINITIONS.—Section 351(i) of the Public Health Service Act (42 U.S.C. 262(i)) is amended—

(1) by striking "In this section, the term 'biological product' means" and inserting the following: "In this section:

"(1) The term 'biological product' means";

(2) in paragraph (1), as so designated, by inserting "protein (except any chemically synthesized polypeptide)," after "allergenic product,"; and

(3) by adding at the end the following:

"(2) The term 'biosimilar' or 'biosimilarity', in reference to a biological product that is the subject of an application under subsection (k), means—

"(A) that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components; and

"(B) there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product.

"(3) The term 'interchangeable' or 'interchangeability', in reference to a biological product that is shown to meet the standards described in subsection (k)(4), means that the biological product may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product.

"(4) The term 'reference product' means the single biological product licensed under subsection (a) against which a biological product is evaluated in an application submitted under subsection (k).".

(c) CONFORMING AMENDMENTS RELATING TO PATENTS.—

(1) PATENTS.—Section 271(e) of title 35, United States Code, is amended—

(A) in paragraph (2)—

(i) in subparagraph (A), by striking "or" at the end;

(ii) in subparagraph (B), by adding "or" at the end; and

(iii) by inserting after subparagraph (B) the following:

"(C)(i) with respect to a patent that is identified in the list of patents described in section 351(l)(3) of the Public Health Service Act (including as provided under section 351(l)(7) of such Act), an application seeking approval of a biological product, or

"(ii) if the applicant for the application fails to provide the application and information required under section 351(l)(2)(A) of such Act, an application seeking approval of a biological product for a patent that could be identified pursuant to section 351(l)(3)(A)(i) of such Act,"; and

(iv) in the matter following subparagraph (C) (as added by clause (iii)),

by striking "or veterinary biological product" and inserting ", veterinary biological product, or biological product";

(B) in paragraph (4)—

(i) in subparagraph (B), by—

(I) striking "or veterinary biological product" and inserting ", veterinary biological product, or biological product"; and

(II) striking "and" at the end;

(ii) in subparagraph (C), by—

(I) striking "or veterinary biological product" and inserting ", veterinary biological product, or biological product"; and

(II) striking the period and inserting ", and";

(iii) by inserting after subparagraph (C) the following:

"(D) the court shall order a permanent injunction prohibiting any infringement of the patent by the biological product involved in the infringement until a date which is not earlier than the date of the expiration of the patent that has been infringed under paragraph (2)(C), provided the patent is the subject of a final court decision, as defined in section 351(k)(6) of the Public Health Service Act, in an action for infringement of the patent under section 351(l)(6) of such Act, and the biological product has not yet

been approved because of section 351(k)(7) of such Act."; and

(iv) in the matter following subparagraph (D) (as added by clause (iii)), by striking "and (C)" and inserting "(C), and (D)"; and

(C) by adding at the end the following:

"(6)(A) Subparagraph (B) applies, in lieu of paragraph (4), in the case of a patent—

"(i) that is identified, as applicable, in the list of patents described in section 351(l)(4) of the Public Health Service Act or the lists of patents described in section 351(l)(5)(B) of such Act with respect to a biological product; and

"(ii) for which an action for infringement of the patent with respect to the biological product—

"(I) was brought after the expiration of the 30-day period described in subparagraph (A) or (B), as applicable, of section 351(l)(6) of such Act; or

"(II) was brought before the expiration of the 30-day period described in subclause (I), but which was dismissed without prejudice or was not prosecuted to judgment in good faith.

"(B) In an action for infringement of a patent described in subparagraph (A), the sole and exclusive remedy that may be granted by a court, upon a

finding that the making, using, offering to sell, selling, or importation into the United States of the biological product that is the subject of the action infringed the patent, shall be a reasonable royalty.

"(C) The owner of a patent that should have been included in the list described in section 351(l)(3)(A) of the Public Health Service Act, including as provided under section 351(l)(7) of such Act for a biological product, but was not timely included in such list, may not bring an action under this section for infringement of the patent with respect to the biological product.".

(2) CONFORMING AMENDMENT UNDER TITLE 28.—Section 2201(b) of title 28, United States Code, is amended by inserting before the period the following: ", or section 351 of the Public Health Service Act".

(d) CONFORMING AMENDMENTS UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT.—

(1) CONTENT AND REVIEW OF APPLICATIONS.—Section 505(b)(5)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)(5)(B)) is amended by inserting before the period at the end of the first sentence the following: "or, with respect to an applicant for approval of a biological product under section 351(k) of the Public Health Service Act, any necessary clinical study or studies".

(2) NEW ACTIVE INGREDIENT.—Section 505B of the Federal Food, Drug, and Cosmetic Act (21

U.S.C. 355c) is amended by adding at the end the following:

"(n) NEW ACTIVE INGREDIENT.—

"(1) NON-INTERCHANGEABLE BIOSIMILAR BIOLOGICAL PRODUCT.—A biological product that is biosimilar to a reference product under section 351 of the Public Health Service Act, and that the Secretary has not determined to meet the standards described in subsection (k)(4) of such section for interchangeability with the reference product, shall be considered to have a new active ingredient under this section.

"(2) INTERCHANGEABLE BIOSIMILAR BIOLOGICAL PRODUCT.—A biological product that is interchangeable with a reference product under section 351 of the Public Health Service Act shall not be considered to have a new active ingredient under this section.".

(e) PRODUCTS PREVIOUSLY APPROVED UNDER SECTION 505.—

(1) REQUIREMENT TO FOLLOW SECTION 351.—Except as provided in paragraph (2), an application for a biological product shall be submitted under section 351 of the Public Health Service Act (42 U.S.C. 262) (as amended by this Act).

(2) EXCEPTION.—An application for a biological product may be submitted under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) if—

(A) such biological product is in a product class for which a biological product in

such product class is the subject of an application approved under such section 505 not later than the date of enactment of this Act; and

(B) such application—

(i) has been submitted to the Secretary of Health and Human Services (referred to in this subtitle as the "Secretary") before the date of enactment of this Act; or

(ii) is submitted to the Secretary not later than the date that is 10 years after the date of enactment of this Act.

(3) LIMITATION.—Notwithstanding paragraph (2), an application for a biological product may not be submitted under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) if there is another biological product approved under subsection (a) of section 351 of the Public Health Service Act that could be a reference product with respect to such application (within the meaning of such section 351) if such application were submitted under subsection (k) of such section 351.

(4) DEEMED APPROVED UNDER SECTION 351.—An approved application for a biological product under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) shall be deemed to be a license for the biological product under such section 351 on the date that is 10 years after the date of enactment of this Act.

(5) DEFINITIONS.—For purposes of this subsection, the term "biological product" has the meaning given such term under section 351 of the Public Health Service Act (42 U.S.C. 262) (as amended by this Act).

(f) FOLLOW-ON BIOLOGICS USER FEES.—

(1) DEVELOPMENT OF USER FEES FOR BIOSIMILAR BIOLOGICAL PRODUCTS.—

(A) IN GENERAL.—Beginning not later than October 1, 2010, the Secretary shall develop recommendations to present to Congress with respect to the goals, and plans for meeting the goals, for the process for the review of biosimilar biological product applications submitted under section 351(k) of the Public Health Service Act (as added by this Act) for the first 5 fiscal years after fiscal year 2012. In developing such recommendations, the Secretary shall consult with—

(i) the Committee on Health, Education, Labor, and Pensions of the Senate;

(ii) the Committee on Energy and Commerce of the House of Representatives;

(iii) scientific and academic experts;

(iv) health care professionals;

(v) representatives of patient and consumer advocacy groups; and

(vi) the regulated industry.

(B) PUBLIC REVIEW OF RECOMMENDATIONS.—After negotiations with the regulated industry, the Secretary shall—

(i) present the recommendations developed under subparagraph (A) to the Congressional committees specified in such subparagraph;

(ii) publish such recommendations in the Federal Register;

(iii) provide for a period of 30 days for the public to provide written comments on such recommendations;

(iv) hold a meeting at which the public may present its views on such recommendations; and

(v) after consideration of such public views and comments, revise such recommendations as necessary.

(C) TRANSMITTAL OF RECOMMENDATIONS.—Not later than January 15, 2012, the Secretary shall transmit to Congress the revised recommendations under subparagraph (B), a summary of the views and comments received under such subparagraph, and any changes made to the recommendations in response to such views and comments.

(2) ESTABLISHMENT OF USER FEE PROGRAM.—It is the sense of the Senate that, based on the recommendations transmitted to Congress by the Secretary pursuant to paragraph (1)(C), Congress

should authorize a program, effective on October 1, 2012, for the collection of user fees relating to the submission of biosimilar biological product applications under section 351(k) of the Public Health Service Act (as added by this Act).

(3) TRANSITIONAL PROVISIONS FOR USER FEES FOR BIOSIMILAR BIOLOGICAL PRODUCTS.—

(A) APPLICATION OF THE PRESCRIPTION DRUG USER FEE PROVISIONS.—Section 735(1)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g(1)(B)) is amended by striking "section 351" and inserting "subsection (a) or (k) of section 351".

(B) EVALUATION OF COSTS OF REVIEWING BIOSIMILAR BIOLOGICAL PRODUCT APPLICATIONS.—During the period beginning on the date of enactment of this Act and ending on October 1, 2010, the Secretary shall collect and evaluate data regarding the costs of reviewing applications for biological products submitted under section 351(k) of the Public Health Service Act (as added by this Act) during such period.

(C) AUDIT.—

(i) IN GENERAL.—On the date that is 2 years after first receiving a user fee applicable to an application for a biological product under section 351(k) of the Public Health Service Act (as added by this Act), and on a biennial basis thereafter until October 1, 2013, the Secretary shall perform an audit of the costs

of reviewing such applications under such section 351(k). Such an audit shall compare—

(I) the costs of reviewing such applications under such section 351(k) to the amount of the user fee applicable to such applications; and

(II)(aa) such ratio determined under subclause (I); to

(bb) the ratio of the costs of reviewing applications for biological products under section 351(a) of such Act (as amended by this Act) to the amount of the user fee applicable to such applications under such section 351(a).

(ii) ALTERATION OF USER FEE.—If the audit performed under clause (i) indicates that the ratios compared under subclause (II) of such clause differ by more than 5 percent, then the Secretary shall alter the user fee applicable to applications submitted under such section 351(k) to more appropriately account for the costs of reviewing such applications.

(iii) ACCOUNTING STANDARDS.—The Secretary shall perform an audit under clause (i) in conformance with the accounting principles, standards, and requirements prescribed by the Comptroller General of the United States under section 3511 of title 31, United State [sic]

Code, to ensure the validity of any potential variability.

(4) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this subsection such sums as may be necessary for each of fiscal years 2010 through 2012.

(g) PEDIATRIC STUDIES OF BIOLOGICAL PRODUCTS.—

(1) IN GENERAL.—Section 351 of the Public Health Service Act (42 U.S.C. 262) is amended by adding at the end the following:

"(m) PEDIATRIC STUDIES.—

"(1) APPLICATION OF CERTAIN PROVISIONS.—The provisions of subsections (a), (d), (e), (f), (i), (j), (k), (l), (p), and (q) of section 505A of the Federal Food, Drug, and Cosmetic Act shall apply with respect to the extension of a period under paragraphs (2) and (3) to the same extent and in the same manner as such provisions apply with respect to the extension of a period under subsection (b) or (c) of section 505A of the Federal Food, Drug, and Cosmetic Act.

"(2) MARKET EXCLUSIVITY FOR NEW BIOLOGICAL PRODUCTS.—If, prior to approval of an application that is submitted under subsection (a), the Secretary determines that information relating to the use of a new biological product in the pediatric population may produce health benefits in that population, the Secretary makes a written request for pediatric studies (which shall include a timeframe for completing such studies), the applicant agrees to the request, such studies are

completed using appropriate formulations for each age group for which the study is requested within any such timeframe, and the reports thereof are submitted and accepted in accordance with section 505A(d)(3) of the Federal Food, Drug, and Cosmetic Act—

> "(A) the periods for such biological product referred to in subsection (k)(7) are deemed to be 4 years and 6 months rather than 4 years and 12 years and 6 months rather than 12 years; and
>
> "(B) if the biological product is designated under section 526 for a rare disease or condition, the period for such biological product referred to in section 527(a) is deemed to be 7 years and 6 months rather than 7 years.

"(3) MARKET EXCLUSIVITY FOR ALREADY-MARKETED BIOLOGICAL PRODUCTS.—If the Secretary determines that information relating to the use of a licensed biological product in the pediatric population may produce health benefits in that population and makes a written request to the holder of an approved application under subsection (a) for pediatric studies (which shall include a timeframe for completing such studies), the holder agrees to the request, such studies are completed using appropriate formulations for each age group for which the study is requested within any such timeframe, and the reports thereof are submitted and accepted in accordance with section 505A(d)(3) of the Federal Food, Drug, and Cosmetic Act—

"(A) the periods for such biological product referred to in subsection (k)(7) are deemed to be 4 years and 6 months rather than 4 years and 12 years and 6 months rather than 12 years; and

"(B) if the biological product is designated under section 526 for a rare disease or condition, the period for such biological product referred to in section 527(a) is deemed to be 7 years and 6 months rather than 7 years.

"(4) EXCEPTION.—The Secretary shall not extend a period referred to in paragraph (2)(A), (2)(B), (3)(A), or (3)(B) if the determination under section 505A(d)(3) is made later than 9 months prior to the expiration of such period.".

(2) STUDIES REGARDING PEDIATRIC RESEARCH.—

(A) PROGRAM FOR PEDIATRIC STUDY OF DRUGS.—Subsection (a)(1) of section 409I of the Public Health Service Act (42 U.S.C. 284m) is amended by inserting ", biological products," after "including drugs".

(B) INSTITUTE OF MEDICINE STUDY.—Section 505A(p) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355b(p)) is amended by striking paragraphs (4) and (5) and inserting the following:

"(4) review and assess the number and importance of biological products for children that are being tested as a result of the amendments made by the Biologics Price Competition and Innovation Act of 2009 and the importance for children, health care providers, parents, and others

of labeling changes made as a result of such testing;

"(5) review and assess the number, importance, and prioritization of any biological products that are not being tested for pediatric use; and

"(6) offer recommendations for ensuring pediatric testing of biological products, including consideration of any incentives, such as those provided under this section or section 351(m) of the Public Health Service Act.".

(h) ORPHAN PRODUCTS.—If a reference product, as defined in section 351 of the Public Health Service Act (42 U.S.C. 262) (as amended by this Act) has been designated under section 526 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb) for a rare disease or condition, a biological product seeking approval for such disease or condition under subsection (k) of such section 351 as biosimilar to, or interchangeable with, such reference product may be licensed by the Secretary only after the expiration for such reference product of the later of—

(1) the 7-year period described in section 527(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360cc(a)); and

(2) the 12-year period described in subsection (k)(7) of such section 351.

SEC. 7003. SAVINGS.

(a) DETERMINATION.—The Secretary of the Treasury, in consultation with the Secretary of Health and Human Services, shall for each fiscal year determine the amount of savings to the Federal Government as a result of the enactment of this subtitle.

(b) USE.—Notwithstanding any other provision of this subtitle (or an amendment made by this subtitle), the savings to the Federal Government generated as a result of the enactment of this subtitle shall be used for deficit reduction.

APPENDIX E

TITLE 28—JUDICIARY AND JUDICIAL PROCEDURE

PART VI—PARTICULAR PROCEEDINGS

CHAPTER 151—DECLARATORY JUDGMENTS

§ 2201. Creation of remedy

(a) In a case of actual controversy within its jurisdiction, except with respect to Federal taxes other than actions brought under section 7428 of the Internal Revenue Code of 1986, a proceeding under section 505 or 1146 of title 11, or in any civil action involving an antidumping or countervailing duty proceeding regarding a class or kind of merchandise of a free trade area country (as defined in section 516A(f)(10) of the Tariff Act of 1930), as determined by the administering authority, any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought. Any such declaration shall have the force and effect of a final judgment or decree and shall be reviewable as such.

(b) For limitations on actions brought with respect to drug patents see section 505 or 512 of the Federal Food, Drug, and Cosmetic Act, or section 351 of the Public Health Service Act.

TITLE 35—PATENTS

PART III—PATENTS AND PROTECTION OF PATENT RIGHTS

CHAPTER 28—INFRINGEMENT OF PATENTS

§ 271. Infringement of patent

(a) Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent.

* * *

(e)(1) It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

(2) It shall be an act of infringement to submit—

(A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent,

(B) an application under section 512 of such Act or under the Act of March 4, 1913 (21 U.S.C. 151-158) for a drug or veterinary biological product which is not primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques and which is claimed in a patent or the use of which is claimed in a patent, or

(C)(i) with respect to a patent that is identified in the list of patents described in section 351(l)(3) of the Public Health Service Act (including as provided under section 351(l)(7) of such Act), an application seeking approval of a biological product, or

(ii) if the applicant for the application fails to provide the application and information required under section 351(l)(2)(A) of such Act, an application seeking approval of a biological product for a patent that could be identified pursuant to section 351(l)(3)(A)(i) of such Act,

if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug, veterinary biological product, or biological product claimed in a patent or

the use of which is claimed in a patent before the expiration of such patent.

(3) In any action for patent infringement brought under this section, no injunctive or other relief may be granted which would prohibit the making, using, offering to sell, or selling within the United States or importing into the United States of a patented invention under paragraph (1).

(4) For an act of infringement described in paragraph (2)—

(A) the court shall order the effective date of any approval of the drug or veterinary biological product involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed,

(B) injunctive relief may be granted against an infringer to prevent the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug, veterinary biological product, or biological product,

(C) damages or other monetary relief may be awarded against an infringer only if there has been commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug, veterinary biological product, or biological product, and

(D) the court shall order a permanent injunction prohibiting any infringement of the patent by the biological product involved in the

infringement until a date which is not earlier than the date of the expiration of the patent that has been infringed under paragraph (2)(C), provided the patent is the subject of a final court decision, as defined in section 351(k)(6) of the Public Health Service Act, in an action for infringement of the patent under section 351(l)(6) of such Act, and the biological product has not yet been approved because of section 351(k)(7) of such Act.

The remedies prescribed by subparagraphs (A), (B), (C), and (D) are the only remedies which may be granted by a court for an act of infringement described in paragraph (2), except that a court may award attorney fees under section 285.

(5) Where a person has filed an application described in paragraph (2) that includes a certification under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), and neither the owner of the patent that is the subject of the certification nor the holder of the approved application under subsection (b) of such section for the drug that is claimed by the patent or a use of which is claimed by the patent brought an action for infringement of such patent before the expiration of 45 days after the date on which the notice given under subsection (b)(3) or (j)(2)(B) of such section was received, the courts of the United States shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any action brought by such person under section 2201 of

title 28 for a declaratory judgment that such patent is invalid or not infringed.

(6)(A) Subparagraph (B) applies, in lieu of paragraph (4), in the case of a patent—

(i) that is identified, as applicable, in the list of patents described in section 351(l)(4) of the Public Health Service Act or the lists of patents described in section 351(l)(5)(B) of such Act with respect to a biological product; and

(ii) for which an action for infringement of the patent with respect to the biological product—

(I) was brought after the expiration of the 30-day period described in subparagraph (A) or (B), as applicable, of section 351(l)(6) of such Act; or

(II) was brought before the expiration of the 30-day period described in subclause (I), but which was dismissed without prejudice or was not prosecuted to judgment in good faith.

(B) In an action for infringement of a patent described in subparagraph (A), the sole and exclusive remedy that may be granted by a court, upon a finding that the making, using, offering to sell, selling, or importation into the United States of the biological product that is the subject of the action infringed the patent, shall be a reasonable royalty.

(C) The owner of a patent that should have been included in the list described in section

351(l)(3)(A) of the Public Health Service Act, including as provided under section 351(l)(7) of such Act for a biological product, but was not timely included in such list, may not bring an action under this section for infringement of the patent with respect to the biological product.

* * *

TITLE 42—THE PUBLIC HEALTH AND WELFARE

CHAPTER 6A—PUBLIC HEALTH SERVICE

SUBCHAPTER II—GENERAL POWERS AND DUTIES

PART F—LICENSING OF BIOLOGICAL PRODUCTS AND CLINICAL LABORATORIES

SUBPART 1—BIOLOGICAL PRODUCTS

§ 262. Regulation of biological products

(a) Biologics license

(1) No person shall introduce or deliver for introduction into interstate commerce any biological product unless—

(A) a biologics license under this subsection or subsection (k) is in effect for the biological product; and

(B) each package of the biological product is plainly marked with—

(i) the proper name of the biological product contained in the package;

(ii) the name, address, and applicable license number of the manufacturer of the biological product; and

(iii) the expiration date of the biological product.

(2)(A) The Secretary shall establish, by regulation, requirements for the approval, suspension, and revocation of biologics licenses.

(B) PEDIATRIC STUDIES.—A person that submits an application for a license under this paragraph shall submit to the Secretary as part of the application any assessments required under section 505B of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355c].

(C) The Secretary shall approve a biologics license application—

(i) on the basis of a demonstration that—

(I) the biological product that is the subject of the application is safe, pure, and potent; and

(II) the facility in which the biological product is manufactured, processed, packed, or held meets standards designed to assure that the biological product continues to be safe, pure, and potent; and

(ii) if the applicant (or other appropriate person) consents to the inspection of the facility

that is the subject of the application, in accordance with subsection (c) of this section.

(D) POSTMARKET STUDIES AND CLINICAL TRIALS; LABELING; RISK EVALUATION AND MITIGATION STRATEGY.—A person that submits an application for a license under this paragraph is subject to sections 505(o), 505(p), and 505-1 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355(o), (p), 355-1].

(3) The Secretary shall prescribe requirements under which a biological product undergoing investigation shall be exempt from the requirements of paragraph (1).

* * *

(i) "Biological product" defined

In this section:

(1) The term "biological product" means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide), or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings.

(2) The term "biosimilar" or "biosimilarity", in reference to a biological product that is the subject of an application under subsection (k), means—

(A) that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components; and

(B) there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product.

(3) The term "interchangeable" or "interchangeability", in reference to a biological product that is shown to meet the standards described in subsection (k)(4), means that the biological product may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product.

(4) The term "reference product" means the single biological product licensed under subsection (a) against which a biological product is evaluated in an application submitted under subsection (k).

* * *

(k) Licensure of biological products as biosimilar or interchangeable

(1) In general

Any person may submit an application for licensure of a biological product under this subsection.

(2) Content

(A) In general

(i) Required information

An application submitted under this subsection shall include information demonstrating that—

(I) the biological product is biosimilar to a reference product based upon data derived from—

(aa) analytical studies that demonstrate that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components;

(bb) animal studies (including the assessment of toxicity); and

(cc) a clinical study or studies (including the assessment of immunogenicity and pharmacokinetics or pharmacodynamics) that are sufficient to demonstrate safety, purity, and potency in 1 or more appropriate conditions of use for which the reference product is licensed and intended to be used and for which licensure is sought for the biological product;

(II) the biological product and reference product utilize the same mechanism or mechanisms of action for the condition or conditions of use prescribed, recommended, or suggested in the proposed labeling, but only to the extent the mechanism or mechanisms of action are known for the reference product;

(III) the condition or conditions of use prescribed, recommended, or suggested in the labeling proposed for the biological product have been previously approved for the reference product;

(IV) the route of administration, the dosage form, and the strength of the biological product are the same as those of the reference product; and

(V) the facility in which the biological product is manufactured, processed, packed, or held meets standards designed to assure that the biological product continues to be safe, pure, and potent.

(ii) Determination by Secretary

The Secretary may determine, in the Secretary's discretion, that an element described in clause (i)(I) is unnecessary in an application submitted under this subsection.

(iii) Additional information

An application submitted under this subsection—

(I) shall include publicly-available information regarding the Secretary's previous determination that the reference product is safe, pure, and potent; and

(II) may include any additional information in support of the application, including publicly-available information with respect to the reference product or another biological product.

(B) Interchangeability

An application (or a supplement to an application) submitted under this subsection may include information demonstrating that the biological product meets the standards described in paragraph (4).

(3) Evaluation by Secretary

Upon review of an application (or a supplement to an application) submitted under this subsection, the Secretary shall license the biological product under this subsection if—

(A) the Secretary determines that the information submitted in the application (or the supplement) is sufficient to show that the biological product—

(i) is biosimilar to the reference product; or

(ii) meets the standards described in paragraph (4), and therefore is interchangeable with the reference product; and

(B) the applicant (or other appropriate person) consents to the inspection of the facility that is the subject of the application, in accordance with subsection (c).

(4) Safety standards for determining interchangeability

Upon review of an application submitted under this subsection or any supplement to such application, the Secretary shall determine the biological product to be interchangeable with the reference product if the Secretary determines that the information submitted in the application (or a supplement to such application) is sufficient to show that—

(A) the biological product—

(i) is biosimilar to the reference product; and

(ii) can be expected to produce the same clinical result as the reference product in any given patient; and

(B) for a biological product that is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch.

(5) General rules

(A) One reference product per application

A biological product, in an application submitted under this subsection, may not be evaluated against more than 1 reference product.

(B) Review

An application submitted under this subsection shall be reviewed by the division within the Food and Drug Administration that is responsible for the review and approval of the application under which the reference product is licensed.

(C) Risk evaluation and mitigation strategies

The authority of the Secretary with respect to risk evaluation and mitigation strategies under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] shall apply to biological products licensed under this subsection in the same manner as such authority applies to biological products licensed under subsection (a).

(6) Exclusivity for first interchangeable biological product

Upon review of an application submitted under this subsection relying on the same reference product for which a prior biological product has received a determination of interchangeability for

any condition of use, the Secretary shall not make a determination under paragraph (4) that the second or subsequent biological product is interchangeable for any condition of use until the earlier of—

(A) 1 year after the first commercial marketing of the first interchangeable biosimilar biological product to be approved as interchangeable for that reference product;

(B) 18 months after—

(i) a final court decision on all patents in suit in an action instituted under subsection (*l*)(6) against the applicant that submitted the application for the first approved interchangeable biosimilar biological product; or

(ii) the dismissal with or without prejudice of an action instituted under subsection (*l*)(6) against the applicant that submitted the application for the first approved interchangeable biosimilar biological product; or

(C)(i) 42 months after approval of the first interchangeable biosimilar biological product if the applicant that submitted such application has been sued under subsection (*l*)(6) and such litigation is still ongoing within such 42-month period; or

(ii) 18 months after approval of the first interchangeable biosimilar biological product if the applicant that submitted such

application has not been sued under subsection (*l*)(6).

For purposes of this paragraph, the term "final court decision" means a final decision of a court from which no appeal (other than a petition to the United States Supreme Court for a writ of certiorari) has been or can be taken.

(7) Exclusivity for reference product

(A) Effective date of biosimilar application approval

Approval of an application under this subsection may not be made effective by the Secretary until the date that is 12 years after the date on which the reference product was first licensed under subsection (a).

(B) Filing period

An application under this subsection may not be submitted to the Secretary until the date that is 4 years after the date on which the reference product was first licensed under subsection (a).

(C) First licensure

Subparagraphs (A) and (B) shall not apply to a license for or approval of—

(i) a supplement for the biological product that is the reference product; or

(ii) a subsequent application filed by the same sponsor or manufacturer of

the biological product that is the reference product (or a licensor, predecessor in interest, or other related entity) for—

(I) a change (not including a modification to the structure of the biological product) that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device, or strength; or

(II) a modification to the structure of the biological product that does not result in a change in safety, purity, or potency.

(8) Guidance documents

(A) In general

The Secretary may, after opportunity for public comment, issue guidance in accordance, except as provided in subparagraph (B)(i), with section 701(h) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 371(h)] with respect to the licensure of a biological product under this subsection. Any such guidance may be general or specific.

(B) Public comment

(i) In general

The Secretary shall provide the public an opportunity to comment on any proposed guidance issued under subparagraph (A) before issuing final guidance.

(ii) Input regarding most valuable guidance

The Secretary shall establish a process through which the public may provide the Secretary with input regarding priorities for issuing guidance.

(C) No requirement for application consideration

The issuance (or non-issuance) of guidance under subparagraph (A) shall not preclude the review of, or action on, an application submitted under this subsection.

(D) Requirement for product class-specific guidance

If the Secretary issues product class-specific guidance under subparagraph (A), such guidance shall include a description of—

(i) the criteria that the Secretary will use to determine whether a biological product is highly similar to a reference product in such product class; and

(ii) the criteria, if available, that the Secretary will use to determine whether a biological product meets the standards described in paragraph (4).

(E) Certain product classes

(i) Guidance

The Secretary may indicate in a guidance document that the science and experience, as of the date of such guidance, with respect to a product or product class (not including any recombinant protein) does not allow approval of an application for a license as provided under this subsection for such product or product class.

(ii) Modification or reversal

The Secretary may issue a subsequent guidance document under subparagraph (A) to modify or reverse a guidance document under clause (i).

(iii) No effect on ability to deny license

Clause (i) shall not be construed to require the Secretary to approve a product with respect to which the Secretary has not indicated in a guidance document that the science and experience, as described in clause (i), does not allow approval of such an application.

(*l*) Patents

(1) Confidential access to subsection (k) application

(A) Application of paragraph

Unless otherwise agreed to by a person that submits an application under subsection (k) (referred to in this subsection as the "subsection (k) applicant") and the sponsor of the application for the reference product (referred to in this subsection as the "reference product sponsor"), the provisions of this paragraph shall apply to the exchange of information described in this subsection.

(B) In general

(i) Provision of confidential information

When a subsection (k) applicant submits an application under subsection (k), such applicant shall provide to the persons described in clause (ii), subject to the terms of this paragraph, confidential access to the information required to be produced pursuant to paragraph (2) and any other information that the subsection (k) applicant determines, in its sole discretion, to be appropriate (referred to in this subsection as the "confidential information").

(ii) Recipients of information

The persons described in this clause are the following:

(I) Outside counsel

One or more attorneys designated by the reference product sponsor who are employees of an entity other than the reference product sponsor (referred to in this paragraph as the "outside counsel"), provided that such attorneys do not engage, formally or informally, in patent prosecution relevant or related to the reference product.

(II) In-house counsel

One attorney that represents the reference product sponsor who is an employee of the reference product sponsor, provided that such attorney does not engage, formally or informally, in patent prosecution relevant or related to the reference product.

(iii) Patent owner access

A representative of the owner of a patent exclusively licensed to a reference product sponsor with respect to the reference product and who has retained a right to assert

the patent or participate in litigation concerning the patent may be provided the confidential information, provided that the representative informs the reference product sponsor and the subsection (k) applicant of his or her agreement to be subject to the confidentiality provisions set forth in this paragraph, including those under clause (ii).

(C) Limitation on disclosure

No person that receives confidential information pursuant to subparagraph (B) shall disclose any confidential information to any other person or entity, including the reference product sponsor employees, outside scientific consultants, or other outside counsel retained by the reference product sponsor, without the prior written consent of the subsection (k) applicant, which shall not be unreasonably withheld.

(D) Use of confidential information

Confidential information shall be used for the sole and exclusive purpose of determining, with respect to each patent assigned to or exclusively licensed by the reference product sponsor, whether a claim of patent infringement could reasonably be asserted if the subsection (k) applicant engaged in the manufacture, use, offering for sale, sale, or importation into the United States of the biological product that is the subject of the application under subsection (k).

(E) Ownership of confidential information

The confidential information disclosed under this paragraph is, and shall remain, the property of the subsection (k) applicant. By providing the confidential information pursuant to this paragraph, the subsection (k) applicant does not provide the reference product sponsor or the outside counsel any interest in or license to use the confidential information, for purposes other than those specified in subparagraph (D).

(F) Effect of infringement action

In the event that the reference product sponsor files a patent infringement suit, the use of confidential information shall continue to be governed by the terms of this paragraph until such time as a court enters a protective order regarding the information. Upon entry of such order, the subsection (k) applicant may redesignate confidential information in accordance with the terms of that order. No confidential information shall be included in any publicly-available complaint or other pleading. In the event that the reference product sponsor does not file an infringement action by the date specified in paragraph (6), the reference product sponsor shall return or destroy all confidential information received under this paragraph, provided that if the reference product sponsor opts to destroy such information, it will

confirm destruction in writing to the subsection (k) applicant.

(G) Rule of construction

Nothing in this paragraph shall be construed—

(i) as an admission by the subsection (k) applicant regarding the validity, enforceability, or infringement of any patent; or

(ii) as an agreement or admission by the subsection (k) applicant with respect to the competency, relevance, or materiality of any confidential information.

(H) Effect of violation

The disclosure of any confidential information in violation of this paragraph shall be deemed to cause the subsection (k) applicant to suffer irreparable harm for which there is no adequate legal remedy and the court shall consider immediate injunctive relief to be an appropriate and necessary remedy for any violation or threatened violation of this paragraph.

(2) Subsection (k) application information

Not later than 20 days after the Secretary notifies the subsection (k) applicant that the application has been accepted for review, the subsection (k) applicant—

(A) shall provide to the reference product sponsor a copy of the application submitted to the Secretary under subsection (k), and such other information that describes the process or processes used to manufacture the biological product that is the subject of such application; and

(B) may provide to the reference product sponsor additional information requested by or on behalf of the reference product sponsor.

(3) List and description of patents

(A) List by reference product sponsor

Not later than 60 days after the receipt of the application and information under paragraph (2), the reference product sponsor shall provide to the subsection (k) applicant—

(i) a list of patents for which the reference product sponsor believes a claim of patent infringement could reasonably be asserted by the reference product sponsor, or by a patent owner that has granted an exclusive license to the reference product sponsor with respect to the reference product, if a person not licensed by the reference product sponsor engaged in the making, using, offering to sell, selling, or importing into the United States of the biological product that is the subject of the subsection (k) application; and

(ii) an identification of the patents on such list that the reference product sponsor would be prepared to license to the subsection (k) applicant.

(B) List and description by subsection (k) applicant

Not later than 60 days after receipt of the list under subparagraph (A), the subsection (k) applicant—

(i) may provide to the reference product sponsor a list of patents to which the subsection (k) applicant believes a claim of patent infringement could reasonably be asserted by the reference product sponsor if a person not licensed by the reference product sponsor engaged in the making, using, offering to sell, selling, or importing into the United States of the biological product that is the subject of the subsection (k) application;

(ii) shall provide to the reference product sponsor, with respect to each patent listed by the reference product sponsor under subparagraph (A) or listed by the subsection (k) applicant under clause (i)—

(I) a detailed statement that describes, on a claim by claim basis, the factual and legal basis of the opinion of the subsection (k) applicant that such patent is invalid,

unenforceable, or will not be infringed by the commercial marketing of the biological product that is the subject of the subsection (k) application; or

(II) a statement that the subsection (k) applicant does not intend to begin commercial marketing of the biological product before the date that such patent expires; and

(iii) shall provide to the reference product sponsor a response regarding each patent identified by the reference product sponsor under subparagraph (A)(ii).

(C) Description by reference product sponsor

Not later than 60 days after receipt of the list and statement under subparagraph (B), the reference product sponsor shall provide to the subsection (k) applicant a detailed statement that describes, with respect to each patent described in subparagraph (B)(ii)(I), on a claim by claim basis, the factual and legal basis of the opinion of the reference product sponsor that such patent will be infringed by the commercial marketing of the biological product that is the subject of the subsection (k) application and a response to the statement concerning validity and enforceability provided under subparagraph (B)(ii)(I).

(4) Patent resolution negotiations

(A) In general

After receipt by the subsection (k) applicant of the statement under paragraph (3)(C), the reference product sponsor and the subsection (k) applicant shall engage in good faith negotiations to agree on which, if any, patents listed under paragraph (3) by the subsection (k) applicant or the reference product sponsor shall be the subject of an action for patent infringement under paragraph (6).

(B) Failure to reach agreement

If, within 15 days of beginning negotiations under subparagraph (A), the subsection (k) applicant and the reference product sponsor fail to agree on a final and complete list of which, if any, patents listed under paragraph (3) by the subsection (k) applicant or the reference product sponsor shall be the subject of an action for patent infringement under paragraph (6), the provisions of paragraph (5) shall apply to the parties.

(5) Patent resolution if no agreement

(A) Number of patents

The subsection (k) applicant shall notify the reference product sponsor of the number of patents that such applicant will provide to the reference product sponsor under subparagraph (B)(i)(I).

(B) Exchange of patent lists

(i) In general

On a date agreed to by the subsection (k) applicant and the reference product sponsor, but in no case later than 5 days after the subsection (k) applicant notifies the reference product sponsor under subparagraph (A), the subsection (k) applicant and the reference product sponsor shall simultaneously exchange—

(I) the list of patents that the subsection (k) applicant believes should be the subject of an action for patent infringement under paragraph (6); and

(II) the list of patents, in accordance with clause (ii), that the reference product sponsor believes should be the subject of an action for patent infringement under paragraph (6).

(ii) Number of patents listed by reference product sponsor

(I) In general

Subject to subclause (II), the number of patents listed by the reference product sponsor under clause (i)(II) may not exceed the number of patents listed by the subsection (k) applicant under clause (i)(I).

(II) Exception

If a subsection (k) applicant does not list any patent under clause (i)(I), the reference product sponsor may list 1 patent under clause (i)(II).

(6) Immediate patent infringement action

(A) Action if agreement on patent list

If the subsection (k) applicant and the reference product sponsor agree on patents as described in paragraph (4), not later than 30 days after such agreement, the reference product sponsor shall bring an action for patent infringement with respect to each such patent.

(B) Action if no agreement on patent list

If the provisions of paragraph (5) apply to the parties as described in paragraph (4)(B), not later than 30 days after the exchange of lists under paragraph (5)(B), the reference product sponsor shall bring an action for patent infringement with respect to each patent that is included on such lists.

(C) Notification and publication of complaint

(i) Notification to Secretary

Not later than 30 days after a complaint is served to a subsection (k) applicant in an action for patent infringement described under this paragraph, the

subsection (k) applicant shall provide the Secretary with notice and a copy of such complaint.

(ii) Publication by Secretary

The Secretary shall publish in the Federal Register notice of a complaint received under clause (i).

(7) Newly issued or licensed patents

In the case of a patent that—

(A) is issued to, or exclusively licensed by, the reference product sponsor after the date that the reference product sponsor provided the list to the subsection (k) applicant under paragraph (3)(A); and

(B) the reference product sponsor reasonably believes that, due to the issuance of such patent, a claim of patent infringement could reasonably be asserted by the reference product sponsor if a person not licensed by the reference product sponsor engaged in the making, using, offering to sell, selling, or importing into the United States of the biological product that is the subject of the subsection (k) application,

not later than 30 days after such issuance or licensing, the reference product sponsor shall provide to the subsection (k) applicant a supplement to the list provided by the reference product sponsor under paragraph (3)(A) that includes such patent, not later than 30 days after such supplement is provided, the subsection (k) applicant shall provide a

statement to the reference product sponsor in accordance with paragraph (3)(B), and such patent shall be subject to paragraph (8).

(8) Notice of commercial marketing and preliminary injunction

(A) Notice of commercial marketing

The subsection (k) applicant shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k).

(B) Preliminary injunction

After receiving the notice under subparagraph (A) and before such date of the first commercial marketing of such biological product, the reference product sponsor may seek a preliminary injunction prohibiting the subsection (k) applicant from engaging in the commercial manufacture or sale of such biological product until the court decides the issue of patent validity, enforcement, and infringement with respect to any patent that is—

(i) included in the list provided by the reference product sponsor under paragraph (3)(A) or in the list provided by the subsection (k) applicant under paragraph (3)(B); and

(ii) not included, as applicable, on—

(I) the list of patents described in paragraph (4); or

(II) the lists of patents described in paragraph (5)(B).

(C) Reasonable cooperation

If the reference product sponsor has sought a preliminary injunction under subparagraph (B), the reference product sponsor and the subsection (k) applicant shall reasonably cooperate to expedite such further discovery as is needed in connection with the preliminary injunction motion.

(9) Limitation on declaratory judgment action

(A) Subsection (k) application provided

If a subsection (k) applicant provides the application and information required under paragraph (2)(A), neither the reference product sponsor nor the subsection (k) applicant may, prior to the date notice is received under paragraph (8)(A), bring any action under section 2201 of title 28 for a declaration of infringement, validity, or enforceability of any patent that is described in clauses (i) and (ii) of paragraph (8)(B).

(B) Subsequent failure to act by subsection (k) applicant

If a subsection (k) applicant fails to complete an action required of the subsection (k) applicant under paragraph (3)(B)(ii), paragraph (5), paragraph (6)(C)(i), paragraph (7),

or paragraph (8)(A), the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of title 28 for a declaration of infringement, validity, or enforceability of any patent included in the list described in paragraph (3)(A), including as provided under paragraph (7).

(C) Subsection (k) application not provided

If a subsection (k) applicant fails to provide the application and information required under paragraph (2)(A), the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of title 28 for a declaration of infringement, validity, or enforceability of any patent that claims the biological product or a use of the biological product.

(m) Pediatric studies

(1) Application of certain provisions

The provisions of subsections (a), (d), (e), (f), (h), (i), (j), (k), (*l*), (n), and (p) of section 505A of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355a(a), (d), (e), (f), (h), (i), (j), (k), (*l*), (n), (p)] shall apply with respect to the extension of a period under paragraphs (2) and (3) to the same extent and in the same manner as such provisions apply with respect to the extension of a period under subsection (b) or (c) of section 505A of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355a(b), (c)].

(2) Market exclusivity for new biological products

If, prior to approval of an application that is submitted under subsection (a), the Secretary determines that information relating to the use of a new biological product in the pediatric population may produce health benefits in that population, the Secretary makes a written request for pediatric studies (which shall include a timeframe for completing such studies), the applicant agrees to the request, such studies are completed using appropriate formulations for each age group for which the study is requested within any such timeframe, and the reports thereof are submitted and accepted in accordance with section 505A(d)(3) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355a(d)(3)]—

(A) the periods for such biological product referred to in subsection (k)(7) are deemed to be 4 years and 6 months rather than 4 years and 12 years and 6 months rather than 12 years; and

(B) if the biological product is designated under section 526 [21 U.S.C. 360bb] for a rare disease or condition, the period for such biological product referred to in section 527(a) [21 U.S.C. 360cc(a)] is deemed to be 7 years and 6 months rather than 7 years.

(3) Market exclusivity for already-marketed biological products

If the Secretary determines that information relating to the use of a licensed biological product

in the pediatric population may produce health benefits in that population and makes a written request to the holder of an approved application under subsection (a) for pediatric studies (which shall include a timeframe for completing such studies), the holder agrees to the request, such studies are completed using appropriate formulations for each age group for which the study is requested within any such timeframe, and the reports thereof are submitted and accepted in accordance with section 505A(d)(3) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355a(d)(3)]—

(A) the periods for such biological product referred to in subsection (k)(7) are deemed to be 4 years and 6 months rather than 4 years and 12 years and 6 months rather than 12 years; and

(B) if the biological product is designated under section 526 [21 U.S.C. 360bb] for a rare disease or condition, the period for such biological product referred to in section 527(a) [21 U.S.C. 360cc(a)] is deemed to be 7 years and 6 months rather than 7 years.

(4) Exception

The Secretary shall not extend a period referred to in paragraph (2)(A), (2)(B), (3)(A), or (3)(B) if the determination under section 505A(d)(3) [21 U.S.C. 355a(d)(3)] is made later than 9 months prior to the expiration of such period.